EXHIBIT A

National Government Services

Medicare

Freedom of Information

National Government Services, Inc.
PO Box 50454
Indianapolis, Indiana 46250-0454
A CMS Contracted Agent

May 7, 2008

Patient Advocates for Medical Justice
Attn: James F. Allen
488 Central Avenue
Suite A
Lancaster, NY 14208

Exhibit A

Refer to: 5701317074
CCN/ DCN: 420736025700-ILA

Dear James F. Allen:

This is in response to your Freedom of Information Act (FOIA) request for a list of hospital names, address and the individual's name who certified for payment of the Ventak Prizm 2 Dr 1861 Defibrillators. After careful search of our files of National Government Services (NGS), i.e., search reasonably calculated to locate records responsive to your request and employing reasonable standards, we were not able to locate any records responsive to your request.

If you consider this response to be an adverse determination, you may appeal. Your appeal should be mailed, within 30 days of the date of this letter, to: The Deputy Administrator, Centers for Medicare & Medicaid Services, Room C5-16-03, 7500 Security Boulevard, Baltimore, Maryland 21244. Please mark your envelope "Freedom of Information Act Appeal," and enclosed a copy of this letter.

The actual charge for conducting NGS's search was $215.00. We are attempting to locate the check (#2725) issued by Myers, Quinn & Schwartz in the amount of $421.00 so that the Freedom of Information Group (FIG), Centers for Medicare & Medicaid Services (in Baltimore, Maryland) can process your refund of $206.00. Questions concerning the refund should be directed to Ms. Melody Hardy, FIG, CMS at (410) 786-5358.

Sincerely yours,

Nicole Moore
Nicole Moore
Freedom of Information

cc: FOIA Officer

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

EXHIBIT B

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N2-20-16
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Strategic Operations and Regulatory Affairs/Freedom of Information Group

Refer to: C08FOI0773 (CAS)

JUN 13 2008

Mr. James F. Allen
Patient Advocates for Medical Justice
488 Central Avenue, Suite A
Lancaster, NY 14208

Exhibit B

Dear Mr. Allen:

This is an interim response to your Freedom of Information Act (FOIA) request dated December 13, 2007, addressed to Ms. Susan Hahn-Reizner in the Centers for Medicare & Medicaid Services' (CMS) Chicago Regional Office for the following information regarding the Ventak Prizm 2 DR 1861 Defibrillators manufactured April 16, 2002 through November 13, 2002 with serial numbers 230796 through 243722 that were paid for by Medicare and Veteran Hospitals:

- Hospital's name, address, and individual's name who certified for payment;
- Left Ventricular Ejection Fraction (EF) number for each device 30% to 40%;
- Left Ventricular Ejection Fraction (EF) number for each device 30% or less; and
- The month, day, and year of the implant/s by serial number.

The Office of Information Services (OIS), CMS has forwarded to the Freedom of Information Group (FIG) a public use file that contains non-identifiable data files of "Implantable Cardioverter Defibrillator (ICD) Implantation data. This file is enclosed. I will provide the results of OIS' search for responsive records within its internal files when those results are received in this FIG.

I understand that on March 24, 2008, the law firm of Myers, Quinn & Schwartz, LLP, forwarded a check in the amount of $421.00 to this agency, as an advance payment for the processing of your request by one of our Medicare contractors, National Government Services (NGS). On May 7, 2008, NGS responded to your request, informing you that no responsive documents were located within their files. Per NGS' letter to you, the actual charge for conducting their search was $215.00. Therefore, I have instructed CMS's Division of Accounting to process a refund to Myers, Quinn & Schwartz, LLP, in the amount of $206.00, the difference between the actual charge for NGS' search ($215.00) and the advance payment of $421.00.

If you have reason to disagree with this decision, you may appeal. Your appeal should be mailed within 30 days of the date of this letter to: The Deputy Administrator, Centers for Medicare &

Medicaid Services, Room C5-16-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. Please mark your envelope "Freedom of Information Act Appeal," and enclose a copy of this letter.

Please direct any questions concerning this response to Ms. Melodye Hardy, of my staff, at (410) 786-5358. Thank you.

Sincerely,

Melodye L. Hardy for

Michael S. Marquis
Director
Freedom of Information Group

Enclosure

cc:
Susan Hahn-Reizner, Region V
Bernadette McDonald, OIS
Mr. James I. Myers, Myers, Quinn & Schwartz, LLP

EXHIBIT C

PFMJ

Patients For
Medical Justice, Ltd.
488 Central Avenue
Suite A
Lancaster, New York 14208
A Not For Profit
1-716-685-2918

U.S. Department of Health/Human Services Centers / Liaison (April 21 2009)
Office of the Regional (2) Administrator
26 Federal Plazas
Room 3811 ***(Freedom of Information) Center / Liason)***
New York New York, 10278-0063

ATTN: Mr. Frank Lifieri **Exhibit C**
Please do not forward, thank you.
FOIA [Title 5 Section 552] Amended [PL- 104-231]

This request does not fall within the nine statutory exemptions.

Expedited Process: An imminent threat to life and physical safety; the requests demonstrates an urgency to inform the remaining 5,000 patients concerning actual governmental lack of activity; and the requested records are needed to meet a deadline in providing this information, as a result of an unexercised Federal FDA Recall.

April 16 2002 through November 13 2002 Guidant Corporation manufactured (12,926) Model: Ventak Prizm 2DR 1861 defibrillators serial number (230796-243722). a total of 7,926 devices have been discovered to have failed April 16 2002-October 5 2007, causing serious injuries, central nerve damage, poisoning, and deaths.

Further it was discovered January14th 2009, by the Irish Medicines Board (IMB), that Guidant Corporation, the "third Quarter" of 2001 had purchased, DERMABOND High Viscosity Line Extension Adhesive, having $4,873,000, million dollars shipped to their Clomnel Ireland Defibrillator Plant by Closure Medical Corporation/Ethicon Inc.

The DERMABOND High Viscosity was injected into the 12,926 devices, of which approximately (10,028) (78%) were reimbursed by Medicare and the Veterans Administration.

The DERMABOND was shipped off labeled, misbranded, adulterated, Non FDA

Approved, and was FDA "Barred" from United States Commerce, and "banned" from sale for internal body use 1998-2009.

January 2009, further FOIA information has uncovered the following, and requires the 20 day release, if you can be kind enough to provide us with that period of time and still provide the request. The DERMABOND High Viscosity was never Human Clinically Tested, the defibrillators have been leaking over a seven year period, leaching, Formaldehyde, D & C Violet # 2 additive, Coal Tar (bituminous coal), Hydrogen Cyanide (asphyxiate), Bisphenol A, Phenol, D-n Octyl Phthalates, 1,4, Benzoquinone, Methyl-Methacrylate-Derivatives, Hydroquinone, and Benzene. The DERMABOND was Non Absorbable, Non Biodegradable, Toxic, and Carcinogen. The product has leached into the body, body tissue, and blood circulation system.

As one of the VA "triple wounded veterans" I am very much aware of its effects, the product had caused additional damage to my heart and developed into permanent arm and hand tremors, before a 2006 removal.

We have enclosed proof of our effort in getting this tragedy exposed, so that you may know, that our request does provide a major compelling response, if you are able to do so, and provide in full our information request at the same time.

Guidant Corporate records have shown approximately 10,028 of the devices were paid by Federal Funds. We have narrowed our request to the bare bones, in placing the 20 days in reach.

Request: We are asking for (Two) (2) Medicare paper or electronic Guidant billing copies and hospital Medicare records, showing the Defibrillator Model Ventak Prism 2DR 1861 device, the (2) heart leads, and physician fee costs, or a total of same on Guidant's billed and Medicare's reimbursed. The reimbursements and billing can be from any state, hospital, and/or physician. We ask only for the serial number, make of device, date implanted, hospital name, payment in full amount, as identifiers. It can be any Medicare payment Guidant Serial Number 230796 through 243722. These devices were implanted and reimbursed, July 18 2002- through November 25th 2003.

Thanking you in advance for your considerations.
Sincerely,

James F. Allen
Director

EXHIBIT D

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N2-20-16
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Strategic Operations and Regulatory Affairs/Freedom of Information Group

APR 22 2009

James Allen
Patient Advocates for Medical Criminal Justice
488 Central Avenue
Suite A
Lancaster, NY 14208

[Exhibit D]

Re: Guidant Corporation Defibrillators

Dear Mr. Allen:

I am acknowledging receipt of your Freedom of Information Act (FOIA) request of November 21, 2008. Our initial review of your request indicates that the responsive documents, if they exist, appear to be of the type that can be directly released to you by the following Centers for Medicare & Medicaid Services (CMS) component(s): the New York Regional Office (Region 2). Accordingly, we have referred your request to the cited office(s) for immediate processing. Questions concerning the status of your request can be directed to **Paul Velez at (212) 616-2533.**

The agency is authorized by law to collect fees for responding to FOIA requests and assumes that you are willing to pay the fees we charge for processing this request. If at anytime the costs for processing your request are estimated to exceed $250.00, the cited office(s) will send you an invoice for the full estimated costs and suspend further processing until payment of the invoice amount is received. If estimated processing costs do not exceed $250.00, the office(s) will send you an invoice for the applicable fee with their response.

Questions or concerns regarding this letter should be directed to Angela Pompey at (410) 786-3153.

Sincerely,

Michael S. Marquis
Director
Freedom of Information Group

Enclosure
cc: **RO-2**
(X Ref: C09FOI0786)

Exhibit E

A major disadvantage of cyanoacrylate adhesives is that one of the degradation products is formaldehyde, which is toxic to the surrounding tissues (see Pani K. C. et al, "The degradation of n-butyl alpha-cyanoacrylate tissue adhesive. II.", Surgery, 1968 March, 63(3), 481-9). For this reason, cyanoacrylates have not found favor with the FDA for internal tissue closure. Only topical skin closure applications have been FDA approved.

Other disadvantages of cyanoacrylate tissue adhesives are their runniness (low viscosity) in uncured form and stiffness when cured.

EXHIBIT E

US Patent 6224622 - Bioabsorable cyanoacrylate tissue adhesives

US Patent Issued on May 1, 2001

Estimated Patent Expiration Date: **September 29, 2019**Estimated Expiration Date is calculated based on simple USPTO term provisions. It does not account for terminal disclaimers, term adjustments, failure to pay maintenance fees, or other factors which might affect the term of a patent.

Abstract Claims Description Full Text

Inventor

- Kotzev, Dimiter Lubomirov

Assignee

- Chemence, Inc.

Application

No. 409312 filed on 09/29/1999

US Classes:

606/214 Chemical bonding material applied to wound edges

Field of Search

606/213, Sutureless closure606/214, Chemical bonding material applied to wound edges606/215,

Exhibit F

EXHIBIT F

U.S. Food and Drug Administration — Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Adverse Event Report

GUIDANT & VENTAK PRIZM 2DR

back to search results

Model Number 1861

Event Description

Rptr has uncovered with respect to the guidant ventak prizm 2dr 1861 devices, manufactured 04/16/2002 - 11/13/2002. (not recalled) the 11,000 devices have the highest rate of failure of any of the guidant devices manufactured to date; in excess of (5%) percent over 600+ adverse events have not been reported. The devices' capacitors, high voltage line insulation and the batteries are and will continue to fail. The capacitors are under size, the batteries are failing 25% to 40% faster than the 7 years stated by guidant. They can fail in a 3 hour period. The insulation is being destroyed by body fluids, this starts to occur 10 months after the implant and the failures show up in the second half of the device longevity.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	GUIDANT & VENTAK PRIZM 2DR
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Device Event Key	671300
MDR Report Key	682033

Event Key	648920
Report Number	MW1037978
Device Sequence Number	1
Product Code	LWS
Report Source	Voluntary
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	02/07/2006
Is This An Adverse Event Report?	No
Device Operator	Invalid Data
Device MODEL Number	1861
Was Device Available For Evaluation?	No Answer Provided
Is the Device an Implant?	Yes
Is this an Explanted Device?	No Answer Provided

Database last updated on April 30, 2009

Exhibit G

EXHIBIT G

FREEDOM OF INFORMATION ANNUAL REPORT – FISCAL YEAR 2005

I. AGENCY: **Centers for Medicare & Medicaid Services**

REPORT PREPARED BY: **Michael S. Marquis**

TITLE: **Director, Freedom of Information Group**

ADDRESS: **Mailstop N2-20-16, 7500 Security Boulevard, Baltimore, MD 21244**

PHONE NUMBER: **(410) 786-5352**

ELECTRONIC ADDRESS FOR REPORT ON THE WORLD WIDE WEB:

http://www.cms.hhs.gov/foia/annrpts.asp

ADDRESS FOR PAPER COPIES OF REPORT: **Same as above**

II. HOW TO MAKE A FOIA REQUEST:

http://www.cms.hhs.gov/foia/making.asp

A. Names, addresses, and telephone numbers of all individual agency components and offices that process FOIA requests (do not include coordinating offices; do not use persons' names – only titles):

http://www.cms.hhs.gov/foia/contacts.asp

B. Brief description of agency's response time range(s):

The agency's response time ranges from as little as 1 day for a simple FOIA request that seeks documents that may be directly released to requesters by CMS program offices, to upwards of 68 months for complex FOIA requests that seek records that must be reviewed against the FOIA exemptions and processed in accordance with the agency's first-in, first-out practice.

C. Brief description of why some requests are not granted:

Requests are not granted in order to preserve the confidentiality of sensitive personal, commercial and government information within CMS's possession and control, and to protect the effective and efficient operations of the agency. To this end, the exemptions most often applicable to CMS records are Exemptions 2, 4, 5, 6, and 7. This agency's decision to deny access to a record (or portion thereof) is made only after application of the Attorney General's "sound legal basis" standard.

Exhibit H

EXHIBIT H

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

January 21, 2009

January 21, 2009

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

SUBJECT: Freedom of Information Act

A democracy requires accountability, and accountability requires transparency. As Justice Louis Brandeis wrote, "sunlight is said to be the best of disinfectants." In our democracy, the Freedom of Information Act (FOIA), which encourages accountability through transparency, is the most prominent expression of a profound national commitment to ensuring an open Government. At the heart of that commitment is the idea that accountability is in the interest of the Government and the citizenry alike.

The Freedom of Information Act should be administered with a clear presumption: In the face of doubt, openness prevails. The Government should not keep information confidential merely because public officials might be embarrassed by disclosure, because errors and failures might be revealed, or because of speculative or abstract fears. Nondisclosure should never be based on an effort to protect the personal interests of Government officials at the expense of those they are supposed to serve. In responding to requests under the FOIA, executive branch agencies (agencies) should act promptly and in a spirit of cooperation, recognizing that such agencies are servants of the public.

All agencies should adopt a presumption in favor of disclosure, in order to renew their commitment to the principles embodied in FOIA, and to usher in a new era of open Government. The presumption of disclosure should be applied to all decisions involving FOIA.

The presumption of disclosure also means that agencies should take affirmative steps to make information public. They should not wait for specific requests from the public. All agencies should use modern technology to inform citizens about what is known and done by their Government. Disclosure should be timely.

I direct the Attorney General to issue new guidelines governing the FOIA to the heads of executive departments and agencies, reaffirming the commitment to accountability and transparency, and to publish such guidelines in the *Federal Register*. In doing so, the Attorney General should review FOIA reports produced by the agencies under Executive Order 13392 of December 14, 2005. I also direct the Director of the Office of Management and Budget to update guidance to the agencies to increase and improve information dissemination to the public, including through the use of new technologies, and to publish such guidance in the *Federal Register*.

This memorandum does not create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

The Director of the Office of Management and Budget is hereby authorized and directed to publish this memorandum in the *Federal Register*.

BARACK OBAMA

# # #

Exhibit I

FOI 08/12/001

14th January 2008

IRISH MEDICINES BOARD

Mr James F. Allen
Patient Advocates Medical Criminal Justice
488 Central Avenue
Suite A
Lancester
New York 14208
United States of America

[EXHIBIT I]

Re: Request for information pursuant to the Freedom of Information Act 1997 & 2003

Dear Mr Allen,

I refer to the request which you made under the Freedom of Information Act 1997 & 2003 for access to records held by the Irish Medicines Board.

(a) The import respectively, "Exempt Medical Products Starting Materials" notification, issued by the IMB (reflected by the PA number) European Commission., S.I 538/539/540/ on the third quarter 2001 Dermabond High Viscosity Line Extension Topical Skin Adhesive.

(b) A copy of any Validation of compliance acknowledgment or updates, performatted spreadsheet or XML files, in reference to the "Third Quarter" 2001 shipment. Product is supplied to the Ireland market and destined for export.

(c) Copy of the Notifying wholesaler Company, Code identifying the "High" Viscosity Dermabond, and authorisation number provided by IMB

(d) Copy of the "Trading Style" company marketing the 2001 "Third quarter" Dermabond High Viscosity Line Extension. "Marketing Authorisation Holder" or "PL Holder"

(e) Country of Authorisation for the pack, per ISO standard, and the batch number for the "Third Quarter" 2001, Dermabond High Viscosity Line Extension Topical Skin Adhesive.

(f) Manufacture/Supplier information from drop down menu, with the identification of the customer to which the exempt medicinal product was supplied the (third Quarter of (2001). Dermabond High Viscosity Line Extension Topical Skin Adhesive.

(g) Any adverse copies submitted to the Pharmacovigilance Section of the IMB, on the Dermabond High Viscosity Line Extension 2001 shipment, including any suspect quality defects, sourced by wholesalers

(h) Copy of any and all product registration, published renewal and updating in Europe for the Dermabond High Viscosity Line Extension, shipped the "Third Quarter" of 2001, and the Dermabond Low Viscosity Adhesive 1997.

(i) Any copies of an authorisation certificate for the Dermabond High Viscosity Line Extension Adhesive "third quarter of 2001 shipment", a class III device, with the batch code and lot serial number.

Bord Leigheasra na hÉireann
Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2
Tel: 353-1-676 4971 Fax: 353-1-676 7836
Website: www.imb.ie

(j) Copy of instructions for installation or connection to the intended medical device, with the sufficient details of it characteristics to identify the correct devices to be used in order to obtain a safe combination.

(k) A copy of the details of the treatment and handling needed, in Ireland, before the device can be used in reference to any reported E-Beam Radiation, "secondary" re-sterilisation process and final assembly of the two (2) Class III medical device combination. (Ireland)

(l) A copy of the conformity with the essential requirements, based on data established in accordance with Annex X

(m) Copies of any information or reports in reference with the "combination product" concerns, provisions, restrictions or performance in accordance, with the intended use. Copies of documentation of the safety, quality, usefulness of the Dermabond High Viscosity Line Extension Adhesive, for internal body use, first shipment the third quarter of 2001.

(n) Copies of the device designed and manufacturing combination, for the purpose of risk reduction of unintentional ingress, of substances, through leaching or degradation into the body and body tissues.

(o) Copy of each of the labelling used in 2001, the first and third quarter shipments of the low and high viscosity Dermabond, distinguishing the "third quarter" "New" Non FDA approved, Dermabond high viscosity line extension adhesive and the fist original, similar Dermabond low viscosity line extension adhesive.

(p) A copy of the CE mark for the Dermabond Low Viscosity Line Extension Adhesive (1997) a copy of the CE mark for the Dermabond High Viscosity Line Extension Adhesive (2001).

Your questions relating to "Brand New "High" Viscosity DERMABOND 2001 "Third Quarter" Shipment."In vitro diagnostic medical device:" are answered in the schedule of records attached with this letter.

The following information is relevant to your request;

The device is manufactured by Closure Medical Corporation, 5250 Green Dairy Road, Raleigh NC 27616, USA and the European Authorised Representative for this device is the Ethicon Division of Johnson and Johnson Medical, PO Box 1988, Simpson Parkway Kirkton Campus Livingston EH54 0AB, Scotland.

Dermabond Viscosity Line Extension Topical Skin Adhesive is a CE Marked medical device. Irish Legislation permits the sale of CE Marked medical devices in Ireland. In accordance with the requirements of Article 11 of 93/42/EEC (Medical Device Directive) the manufacturer can only affix a CE mark to this device following conformity assessment of the product by a Notified Body. The conformity assessment of this product was performed by BSI (British Standards Institute) and their US address is 12110 Sunset Hill Road, Suite 200, Reston, VA 20190, USA.

1. Schedule of records

The schedule is attached at the end of this letter and shows the records that the Irish Medicines Board considers relevant to your request. It also gives you a summary and overview of the decision as a whole.

The schedule describes each record, and indicates whether the record is released in full, released with deletions or refused. Where records have been refused in full or in part, the schedule refers to the relevant sections of the FOI Act which apply.

2. Records to which access is granted

You have sought access to photocopies of the records concerned. The Irish Medicines Board is please to offer access in that form. Accordingly, I enclose with this letter copies of the records released in full or released with deletions which are identified in the attached schedule

3. Rights of appeal

You may appeal this decision by writing to the Irish Medicines Board at the address given below.

Chief Executive Officer,
Irish Medicines Board,
Earlsfort Centre,
Earlsfort Terrace,
Dublin 2.

You must make your appeal **within 4 weeks** from the date of this notification. The making of a late appeal may be permitted in some circumstances. The appeal process, known as internal review, will involve a complete reconsideration of the matter by the Chief Executive of the Irish Medicines Board. The decision on internal review of your case will be given within 3 weeks of receipt of your letter.

Yours sincerely,

Jackie Cottell

Jackie Cottell
Information Officer

Exhibit J

Freedom of Information Act (FOIA)

Overview

The Freedom of Information Act (FOIA) affords requesters all of the rights accorded to them by law, including the right of access to any non-privileged agency record, and to protect from inappropriate disclosure any agency record that may and should be withheld under the statute. CMS establishes implementing policies and procedures, provides authoritative advice and guidance, receives and processes FOIA requests for records. CMS oversees component and Medicare contractor compliance to the statutes, and offers a customer service to the members of the public.

Freedom of Information Act Contacts

Refer to the links section below for information on the Freedom of Information Group's (FIG) contacts including:

1. Freedom of Information Group, Baltimore, MD

2. CMS Regional Office Coordinators

3. Intermediary and Carrier Directory

EXHIBIT J

The Freedom of Information Act

The Freedom of Information Act (FOIA), found in Title 5 of the United States Code, section 552, was enacted in 1966 and provides that, upon request from any person, a Federal agency must release any agency record unless that record falls within one of the nine statutory exemptions and three exclusions. The FOIA binds only Federal agencies, and covers only records in the possession and control of Federal agencies. For additional information on FOIA, refer to the section in the *Related Links Outside CMS*.

The Freedom Of Information Act As Amended By Public Law 104-231

The FOIA was amended recently by PL 104-231. Click on the link below to view the statute.

A Citizen's Guide on Using the Freedom of Information Act and the Privacy Act of 1974 to Request Government Records

This report explains how to use the Freedom of Information Act and the Privacy Act of 1974. It reflects all changes to the laws made since 1996. This Guide is intended to serve as general introduction to the Freedom of Information Act and the Privacy Act. It offers neither a comprehensive explanation of the details of these acts, nor an analysis of case law. The Guide will, however, enable those who are unfamiliar with the laws to understand the process and to make a request. In addition, the complete text of each law is included in an appendix. To view the Guide, select the link in the section, *Related Links Outside CMS.*

Downloads

CMS FOIA and Policy and Procedural Guide [PDF, 2,581 KB]

Related Links Inside CMS

Privacy Act of 1974

Freedom of Information Act

Information Security: Laws & Regulations

Related Links Outside CMS

Freedom of Information Act

Freedom of Information Act, amended by Public Law 104-231

Citizen's Guide on Using the Freedom of Information Act and the Privacy Act of 1974 to Request Government Records [PDF, 514 KB]

Page Last Modified: 03/05/2009 9:59:40 AM
Help with File Formats and Plug-Ins

Submit Feedback

Exhibit K

the meaning of the Medicare program. Thus, Medicare coverage was denied for devices which were under an IDE and had not yet received premarket notification clearance and or premarket approval.

Exhibit K

Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices September 15, 1995 (D95-2)

[Exhibit K]

IDE Guidance Memorandum #95-2

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

Office of Device Evaluation (HFZ-400)

Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices

ODE Review Staff

Purpose

The purpose of this memorandum is to establish procedures for fulfilling FDA's responsibilities as defined in the FDA/HCFA Interagency Agreement (IA) pertaining to the reimbursement of investigational devices.

Background

According to the statute governing the Medicare program (Section 1862 (a)(1)(A) of the Social Securities Act), the Health Care Financing Administration (HCFA) is permitted to reimburse for medical services and products that are deemed "reasonable and necessary" for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member. The Medicare program has historically interpreted the statutory terms "reasonable and necessary" to mean that a service or medical device must be safe and effective, medically necessary and appropriate, and not experimental in order to qualify for reimbursement. For Medicare coverage purposes, the term "experimental" has been used synonymously with the term "investigational." Therefore, with rare exception, an FDA-approved Investigational Device Exemption (IDE) application served as an indication that the device was not "reasonable and necessary" within

Exhibit L

[Exhibit L]

	Current Projections	Alternative Projections
Unified Budget Surplus in 2002	173	200 225 250
Total Medicare Spending in 2002	254	No change
HI Trust Fund Balance in 2002	234	No change
Increase in Benefits Paid in 2011 Compared to 2002	196	No change
HI Exhaustion Date	2029	No change

The gap between Medicare's dedicated receipts and spending will widen as the baby boomers enter the program. Between now and 2030 the number of persons age 65 and older is expected to increase rapidly from 40 million to 77 million. Expenses will also rise because healthcare costs are expected to increase.

There is a common misperception that there is a Medicare surplus and that Congress must take action to preserve its assets. There is no Medicare surplus. Any excess cash collected from the payroll tax that is not used to provide hospital insurance is used for other Medicare spending such as doctor bills, which are not fully covered by premiums paid by beneficiaries. These premiums cover only about 25 percent of doctor bills and other costs paid from Medicare's other trust fund, the Part B, or Supplementary Medical Insurance trust fund. Additional funds come from the general fund of the government to cover Medicare's remaining costs. In fact, in 2002, without this general fund transfer, Medicare would face a $48 billion shortfall.

Chart 4. Medicare 2002 Shortfall. This chart shows that payroll taxes and premiums do not cover the entire cost of the medicare program. Premiums from medicare Part B, or the Supplementary Medicare Insurance trust fund, cover only about 25 percent of the program's costs, resulting in a shortfall of $48 billion in 2002. Additional funds must come from the general fund of the government to cover Medicare's remaining costs.

MEDICARE TRUST FUNDS [1]

Every dollar of Medicare funding is spent on Medicare and Medicare alone in the President's budget.

The President's budget fully funds both the Medicare Hospital Insurance (HI) Trust Fund and Medicare benefits for our nation's seniors and disabled, as required by law. Under the President's budget, the Medicare HI Trust Fund balance will increase by $537 billion, and Medicare spending will reach the highest levels ever, nearly doubling over the next 10 years. The President's budget protects the Medicare program for future generations and continues the promise of full financing of Medicare benefits.

In 2001 the Medicare HI Trust Fund, which provides hospital insurance to seniors and is funded by a payroll tax, will collect $175 billion and spend $143 billion, yielding a $32 billion surplus. Federal law requires that this $32 billion overage be credited to the Medicare HI Trust Fund. However, the federal government does not keep actual dollars in the Medicare Trust Fund, or any other trust fund for that matter. Instead, it lends the money to itself and issues an IOU, in the form of a Treasury security, to the trust fund.

In sum, over the period 2002 to 2011, the projected HI accounting "surplus" of $537 billion is overwhelmed by the SMI's shortfall of $1.14 trillion. There is actually a Medicare shortfall in every year, with a total of $603 billion over the next 10 years. The President has proposed a unified trust fund to make it easier to understand Medicare finances.

TABLE 4. MEDICARE FULLY FUNDED UNDER ALL BUDGET SCENARIOS

(Dollar amounts in billions)

	Current Projections	Alternative Projections
Unified Budget Surplus in 2002	173	200 225 250
Total Medicare Spending in 2002	254	——— No change ———
HI Trust Fund Balance in 2002	234	——— No change ———
Increase in Benefits Paid in 2011 Compared to 2002	196	——— No change ———
HI Exhaustion Date	2029	——— No change ———

The gap between Medicare's dedicated receipts and spending will widen as the baby boomers enter the program. Between now and 2030 the number of persons age 65 and older is expected to increase rapidly from 40 million to 77 million. Expenses will also rise because healthcare costs are expected to increase.

There is a common misperception that there is a Medicare surplus and that Congress must take action to preserve its assets. There is no Medicare surplus. Any excess cash collected from the payroll tax that is not used to provide hospital insurance is used for other Medicare spending such as doctor bills, which are not fully covered by premiums paid by beneficiaries. These premiums cover only about 25 percent of doctor bills and other costs paid from Medicare's other trust fund, the Part B, or Supplementary Medical Insurance trust fund. Additional funds come from the general fund of the government to cover Medicare's remaining costs. In fact, in 2002, without this general fund transfer, Medicare would face a $48 billion shortfall.

Chart 4. Medicare 2002 Shortfall. This chart shows that payroll taxes and premiums do not cover the entire cost of the medicare program. Premiums from medicare Part B, or the Supplementary Medicare Insurance trust fund, cover only about 25 percent of the program's costs, resulting in a shortfall of $48 billion in 2002. Additional funds must come from the general fund of the government to cover Medicare's remaining costs.

Exhibit M

P960052/S004 **12/31/02** **180-Day**	Dermabond Topical Skin Adhesive, High Viscosity Product	Closure Medical Corporation Raleigh, NC 27616	Approval for the addition of a higher viscosity product. The device, as modified, will be marketed under the trade name High Viscosity Dermabond Topical Skin Adhesive and is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. High Viscosity DERMABOND adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

Exhibit M

PMA Final Decisions Rendered for December 2002

See Related Information

Some of the documents on this section of the CDRH Website are available only in PDF format and may not be accessible to those with certain disabilities. If you cannot access the documents you are interested in, please use the accessibility link for assistance. Below are Premarket Approvals (PMA), Product Development Protocols (PDP), Supplement and Notice Decisions for August 2000. This list is generated on a monthly basis.

PMA Original Approvals

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
P010055 12/23/02	ProstaLund® CoreTherm™ System Microwave Thermotherapy for BPH	ProstaLund Operations AB Lund, Sweden SE-226 60	Approval for the ProstaLund® CoreTherm™ Microwave Thermotherapy System. The ProstaLund® CoreTherm™ is a non-surgical, minimally invasive device intended to relieve symptoms associated with symptomatic Benign Prostatic Hyperplasia (BPH) by ProstaLund® Feedback Treatment® (PLFT®), and is indicated for men with prostate size of 30 to 100g and prostatic urethra length ≥ 35 mm.
P020007 12/18/02	Medtronic AVE Bridge™ Extra Support Over-the-Wire (OTW) Renal Stent System	Medtronic AVE, Inc. Santa Rosa, CA 95403	Approval for the Medtronic AVE Bridge™ Extra Support Over-the-Wire (OTW) Renal Stent System. The device is indicated for use in patients with atherosclerotic disease of the renal arteries

Exhibit N

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, N2-20-16
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Strategic Operations and Regulatory Affairs/Freedom of Information Group

Refer to: C08FOI0773

MAR 10 2008

Exhibit N

Mr. James F. Allen
Patients for Medical Justice
488 Central Avenue, Suite A
Lancaster, New York 14208

Dear Mr. Allen:

This is in response to your January 29, 2008 letter addressed to Ms. Susan Hahn-Reizner, Freedom of Information Coordinator, Chicago Regional Office (Region V), Centers for Medicare & Medicaid Services (CMS) requesting a waiver of the fees associated with processing your December 13, 2007 Freedom of Information Act (FOIA) request for certain information concerning Ventak Prizm 2 Dr 1861 Defibrillators. Ms. Hahn-Reizner referred your fee waiver request to this office for disposition in accordance with Department of Health and Human Services' FOIA regulations found at 45 C.F.R. § 5.45(e) which provide that only FOIA Officers may make the decision whether to waive or reduce fees.

The statutory standard for evaluating a fee waiver request is whether release of the information "is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester," in which event, a fee waiver or reduction is required by law. 5 U.S.C. 552(a)(4)(A)(iiii).

I considered the following six factors in my determination as to whether your request satisfies the statutes two-part standard: (1) whether the requested records concern the operations or activities of the government; (2) whether the disclosure is likely to contribute to an understanding of government operations or activities; (3) whether disclosure of the requested information will contribute to the understanding of the general public; (4) whether the disclosure is likely to contribute "significantly" to public understanding of government operations or activities; (5) whether the requester has a commercial interest that would be furthered by the requested disclosure; and (6) whether any such commercial interest outweighs the public interest in disclosure. Factors 1 through 4 are relevant in determining the "public interest" and factors 5 and 6 are relevant in determining whether disclosure is or is not in the commercial interest of the requester.

On the basis of the information available to me, including the enclosures to your January 29th letter, I have concluded that your fee waiver request fails to meet the public interest standard, and I must deny your request for a waiver of the fees associated with the processing of your December 13th FOIA request.

To explain, your fee waiver request falls short of meeting the public interest standard, in relation to factor 3. In analyzing factor 3, I specifically considered whether you intend to disseminate the information to the general public and how such dissemination would be carried out. I note that while you state that "this information will be totally available to the American public and specifically Medicare patients," and that your intent is to publish the requested information in a useful forum, you have not provided specific and detailed information that identifies the forum and its use. In a telephone conversation on March 5, 2008, Ms. Melodye Hardy, of my staff, requested that you provide written information to this office concerning your means of dissemination so that such information could be factored into my decision. I understand that you indicated to Ms. Hardy that you would not provide any additional written support for your waiver request. Therefore, my decision is based solely upon the written information at hand.

Finally, you are advised that since your request was directed to CMS's Chicago Regional Office, processing to date has been limited to Medicare Part A contractors within that Region's jurisdiction. If your request was intended to be national or multi-regional in scope, please advise Ms. Hardy so that cost estimates can be obtained from all involved Medicare Part A contractors. Ms. Hardy can be reached at (410) 786-5358 or Melodye.Hardy@cms.hhs.gov. In light of my decision to deny your fee waiver request, you will be responsible for payment of all fees assessed if you authorize our continued processing of your request.

If you disagree with this decision to deny your request for a waiver of fees, you may appeal. Your appeal should be mailed within 30 days of the date of this letter to: The Deputy Administrator, Centers for Medicare & Medicaid Services, Room C5-16-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. Mark your envelope "Freedom of Information Act Appeal" and enclose a copy of this letter with your appeal.

(The enclosures to your January 29th letter will be returned to you, per your request, when all fee waiver issues are settled.)

Sincerely yours,

Michael S. Marquis
Director
Freedom of Information Group

cc: Susan Hahn-Reizner, Region V
Gwen Pershing, National Government Services
John Noel, Noridian Administrative Services LLC

Exhibit O

UNITED STATES COMMISSION ON CIVIL RIGHTS
WASHINGTON, D.C. 20425

OFFICE OF STAFF DIRECTOR

March 25, 2008

Exhibit O

James F. Allen
Patients for Medical Justice
488 Central Avenue
Suite A
Lancaster, New York 14086

Dear Mr. Allen:

We received your letter requesting assistance with Michael S. Marquis, the FOIA Officer at the Centers for Medicare & Medicaid Services. We suggest you contact the FOIA Officer for the Department of Health and Human Services of which the Centers for Medicare & Medicaid Services are part.

Department of Health and Human Services
Robert Eckert
Director, FOIA/Privacy Division
Room 5416, Mary E. Switzer Building
330 C Street, S.W.
Washington, D.C. 20201
telephone number: (202) 690-7453
fax number: (202) 690-8320

We would also like to make you aware that the Department of Justice provides information on FOIA at its website that might be of assistance to you. See the following: http://www.usdoj.gov/oip/04_7.html

I trust this information is of assistance to you.

Sincerely,

EMMA GONZALEZ-JOY
FOIA Officer

Exhibit P

FOIA Update
Vol. VIII, No. 1
1987

Exhibit P

New Fee Waiver Policy Guidance

[The following is the full text of the Department of Justice fee waiver policy guidance memorandum issued to the heads of all federal agencies on April 2, 1987, by Stephen J. Markman, Assistant Attorney General, Office of Legal Policy.]

Under the Freedom of Information Reform Act of 1986, Pub. L. No. 99-570, §§ 1801-1804, 100 Stat. 3207, 3207-48 (1986), all federal agencies subject to the Freedom of Information Act ("FOIA") are required to promulgate revised regulations implementing the FOIA's amended fee and fee waiver provisions. The Office of Management and Budget has prepared Uniform Freedom of Information Act Fee Schedule and Guidelines ("OMB Fee Guidelines"), 52 Fed. Reg. 10011 (March 27, 1987), and the revised FOIA fee regulations issued by each agency must conform with the OMB Fee Guidelines.

One provision of the Freedom of Information Reform Act requires that individual agency regulations set forth "procedures and guidelines for determining when such fees should be waived or reduced." 5 U.S.C. § 552(a)(4)(A)(i) (effective April 25, 1987). The OMB Fee Guidelines address neither this requirement nor the new statutory standard governing the waiver of FOIA fees, 5 U.S.C. § 552(a)(4)(A)(iii).

To assist agencies in implementing this provision, and in accordance with the statutory responsibility of the Department of Justice to encourage agency compliance with the FOIA, *see* 5 U.S.C. § 552(e), I am providing the following advisory fee waiver policy guidance to all federal agencies on behalf of the Attorney General, *see* 28 C.F.R. § 0.23(c) (1986). (1)

The Department of Justice stands committed to encouraging agencies to waive fees under the FOIA whenever the statutory fee waiver standard is met. By the same token, of course, agencies also are expected to respect the balance drawn in the statute, safeguarding federal funds by granting waivers or reductions only where it is determined that the statutory standard is satisfied.

This guidance advises agencies of the factors which should be considered in applying the new statutory fee waiver standard. As the Supreme Court has made clear in interpreting the FOIA, the Act is to be applied according to "[t]he plain language of the statute itself." (2) Part I of this memorandum addresses the new statutory fee and fee waiver structure, Part II sets forth specific fee waiver factors recommended for each agency to include in its revised FOIA regulations, and Part III explains the derivation and application of those factors under the language of the new statutory fee waiver standard.

I. NEW STATUTORY FEE WAIVER STANDARD

Prior to its amendment in 1986, the FOIA provided for the charging of fees for document search and duplication, and further provided that such fees should be waived or reduced wherever that was found to be "in the public interest because furnishing the information can be considered as primarily benefiting the general public." 5 U.S.C. § 552(a)(4)(A) (1982).

As amended, effective April 25, 1987, the FOIA establishes three levels of fees that may be charged: Depending on the identity of the requester and his use of requested information, 5 U.S.C. § 552(a)(4)(A)(ii) provides for the charging of fees for document duplication alone for certain categories of requesters; fees for search time and duplication, and for review time as well, in the case of commercial requesters; and, for all other requesters, fees for search time and duplication. A separate provision of the amended FOIA provides for the waiver or reduction of applicable fees upon the satisfaction of a revised statutory fee waiver standard.

The FOIA's new fee waiver standard, found at 5 U.S.C. § 552(a)(4)(A)(iii), more specifically defines the term "public interest" and provides:

> Documents shall be furnished without any charge or at a charge reduced below the fees established under clause (ii) if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

This new statutory fee waiver standard thus sets forth two basic requirements, both of which must be satisfied before fees properly assessable can be waived or reduced. (3) First, it must be established that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government." Second, it must be established that "disclosure of the information . . . is not primarily in the commercial interest of the requester."

Where these two statutory requirements are satisfied, based upon information supplied by a requester or otherwise made known to an agency, the waiver or reduction of a FOIA fee is compelled by the statute and should be granted freely and promptly by the agency. (4) Where one or both of these requirements is not satisfied, a fee waiver is not warranted under the statute.

II. SUMMARY OF FEE WAIVER GUIDANCE

The Department of Justice recommends that each federal agency employ the following six factors when, as required by the Freedom of Information Reform Act, it revises its regulations to set forth "guidelines for determining when [FOIA] fees should be waived or reduced." The remainder of this guidance memorandum elaborates upon the derivation and application of these factors. In summary, these factors are as follows:

A. Disclosure of the Information "is in the Public Interest Because it is Likely to Contribute Significantly to Public Understanding of the Operations or Activities of the Government."

(1) **The subject of the request:** Whether the subject of the requested records concerns "the operations or activities of the government";

(2) **The informative value of the information to be disclosed:** Whether the disclosure is "likely to contribute" to an understanding of government operations or activities;

(3) **The contribution to an understanding of the subject by the general public likely to result from disclosure:** Whether disclosure of the requested information will contribute to "public understanding"; and

(4) **The significance of the contribution to public understanding:** Whether the disclosure is likely to contribute "significantly" to public understanding of government operations or activities.

B. Disclosure of the Information "is Not Primarily in the Commercial Interest of the Requester."

(1) **The existence and magnitude of a commercial interest:** Whether the requester has a commercial interest that would be furthered by the requested disclosure; and, if so

(2) **The primary interest in disclosure:** Whether the magnitude of the identified commercial interest of the requester is sufficiently large, in comparison with the public interest in disclosure, that disclosure is "primarily in the commercial interest of the requester."

III. APPLICATION OF FEE WAIVER FACTORS

The six enumerated factors elaborated upon below are those which the new statutory standard, by its plain language, requires agencies to take into consideration in determining whether the two basic requirements for a fee waiver or reduction are met. They should be applied to fee waiver requests sequentially, on a case-by-case basis.

A. Disclosure of the Information "is in the Public Interest Because it is Likely to Contribute Significantly to Public Understanding of the Operations or Activities of the Government."

This first part of the new statutory fee waiver standard sets forth a specific definition of the crucial term "public interest." As distinguished from the previous statutory language, which spoke only generally of a disclosure's benefit to the public, this language specifies the public benefit resulting from disclosure to be considered in making fee waiver determinations. In so doing, it establishes a more particular "public interest" standard to be met as a threshold matter, with the result that some disclosures that might have met the more general public interest standard under the previous standard will not satisfy the standard as revised.

The plain language of this first basic requirement encompasses four related considerations. A careful analysis of them, in sequence, is necessary to lead to a proper determination of whether a request satisfies the statute's specific "public interest" requirement.

(1) **The Subject of the Request:** Whether the Subject of the Requested Records Concerns "the Operations or Activities of the

Government."

Initially, an agency should consider whether the subject of the requested records, in the context of the request, concerns the operations or activities of the government in the first place. A more general public interest in the subject of a record, which was the broader focus of the previous statutory standard, no longer is sufficient. Rather, the subject matter of the requested records must specifically concern identifiable operations or activities of the federal government -- with a connection between them that is direct and clear, not remote or attenuated. As the D.C. Circuit Court of Appeals recently indicated in applying the predecessor fee waiver standard, "the links between furnishing the requested information and benefiting the general public" should not be "tangential," "less than obvious," or "at best tenuous." *National Treasury Employees Union v. Griffin*, 811 F.2d 644, 647-48 (D.C. Cir. 1987); *see also American Federation of Government Employees v. Department of Commerce*, 632 F. Supp. 1272, 1278 (D.D.C. 1986) (claims of public benefit under previous standard rejected as "too ephemeral").

While in most cases records possessed by a federal agency will likely meet this threshold, there are cases in which requested records do not directly concern government operations or activities and therefore would fail to meet it. A prime example can be records in an agency's possession that were generated by a non-government entity, records which often are sought for their intrinsic informational content alone. Where requesters manifestly seek records for their intrinsic content apart from their informative value with respect to specific government operations or activities, they can hardly hold real prospect for contributing to public understanding of those operations or activities. In the case of such requests, whether for records submitted to an agency or generated by it, this threshold consideration is not satisfied.

(2) **The Informative Value of the Information to be Disclosed:** Whether the Disclosure is "Likely to Contribute" to an Understanding of Government Operations or Activities.

Next, an agency should determine whether the disclosure in question is likely to contribute to an understanding of government operations or activities. This requires an analysis of the substantive content of the disclosable portions of the records requested, in order to determine whether their disclosure will in fact be informative regarding the particular government activities or operations that are connected to the subject matter of the request. The agency to whose operations the records pertain ordinarily is in the best position to make this determination.

Although the subject matter of a FOIA request may directly concern certain government operations or activities, if the records (or record portions) which can be released in response to that request contain nothing that is meaningfully informative on such operations or activities, then the requested FOIA disclosure would not at all contribute to an understanding of them. Further, even where information is meaningful in and of itself, it does not necessarily hold great potential for contributing to increased public understanding. Thus, the foundation for a proper fee waiver analysis must be a close appraisal of the particular information that is to be disclosed, with careful attention to the potential that it holds for contributing to the public understanding of government operations or activities.

In this connection, an agency should also consider whether the requested information is already in the public domain, either in a duplicative or a substantially identical form. If it is, then disclosure of the information would not be likely to contribute to an understanding of government operations or activities, as nothing new would be added to the public record. This principle properly applied under the previous statutory fee waiver standard, *see, e.g., Blakey v. Department of Justice*, 549 F. Supp. 362, 364-65 (D.D.C. 1982), *aff'd mem.*, 720 F.2d 215 (D.C. Cir.

1983), and should continue to be applicable.

(3) **The Contribution to an Understanding of the Subject by the Public Likely to Result from Disclosure:** Whether Disclosure of the Requested Information Will Contribute to "Public Understanding."

An agency next should consider whether disclosure will contribute to the understanding of the public at large, as opposed to the individual understanding of the requester or a narrow segment of interested persons. *See Crooker v. Department of the Army*, 577 F. Supp. 1220, 1223 (D.D.C. 1984) (rejecting fee waiver under previous standard for information of interest to "a small segment of the scientific community," which would not "benefit the public at large"), *appeal dismissed as frivolous*, No. 84-5089 (D.C. Cir. June 22, 1984).

The proper focus thus must be on the contribution to public understanding, rather than personal benefit to be derived by the requester. *See National Treasury Employees Union v. Griffin*, 811 F.2d at 648 (rejecting "union's suggestion that its size insures that any benefit to it amounts to a public benefit"). Thus, a requester's indigency, for example, does not entitle him to a fee waiver; there must be a credible showing of a contribution to the public's understanding that would result from disclosure. *Cf. Ely v. United States Postal Service*, 753 F.2d 163, 165 (D.C. Cir.) (holding under previous fee waiver standard that indigency alone did not satisfy statutory requirement that disclosure must primarily benefit general public), *cert. denied*, 471 U.S. 1106 (1985). This is only appropriate, given that a fee waiver necessarily involves the "expenditure of public funds." *Id.*; *see also Burriss v. CIA*, 524 F. Supp. 448, 449 (M.D. Tenn. 1981) ("[I]n simple terms, the public should not foot the bill unless it will be the primary beneficiary of the [disclosure].").

For purposes of this analysis, the identity of the requester should be considered, in order for an agency to determine whether the requester is in a position to contribute to public understanding through the requested disclosure. A requester's identity and qualifications -- *e.g.*, expertise in the subject area and ability and intention to disseminate the information to the general public -- should be evaluated. *Accord Eudey v. CIA*, 478 F. Supp. 1175, 1177 (D.D.C. 1979) (articulating such approach under previous fee waiver standard). Specialized knowledge often is required to extract, synthesize and effectively convey information to the public and requesters vary in their ability to do so. Where not readily apparent to an agency, requesters should be asked to describe specifically their qualifications, the nature of their research, the purposes for which they intend to use the requested information, and their intended means of dissemination to the public.

Bare assertions by requesters that they are "researchers" or have "plans to author a book" are insufficient evidence that a contribution to understanding by the general public will ultimately result from a disclosure. *See Burriss v. CIA*, 524 F. Supp. at 449 (holding such assertions insufficient under prior law to establish that general public would be ultimate beneficiary of disclosure). It reasonably may be presumed, however, that those "representatives of the news media," as defined in the OMB Fee Guidelines, [(5)] who have access to the means of public dissemination, readily will be able to satisfy this aspect of the statutory requirement. *Accord FOIA Update*, Fall 1983, at 14.

This consideration is not satisfied simply because a fee waiver request is made by a library or other record repository, or a requester who intends merely to disseminate information to such an institution. Such requests, like those of other requesters, should be analyzed to identify a particular person who will actually use the requested information in scholarly or other analytic work and then disseminate it to the general public; absent that, it cannot be determined that disclosure to the requester will contribute to the public's understanding of government

operations or activities. *Accord National Treasury Employees Union v. Griffin*, 811 F.2d at 647 (observing under previous standard that public benefit should be "identified with reasonable specificity"). Thus, such requesters should make the same fee waiver showing that a person would have to make to obtain a fee waiver directly, including a representation by that person of intent to perform the work involved.

(4) **The Significance of the Contribution to Public Understanding:** Whether the Contribution to Public Understanding of Government Operations or Activities Will be "Significant."

Lastly, an agency is required by the statute to determine whether an identified contribution to public understanding of government operations or activities will be a "significant" one, *i.e.*, such that the general public's understanding of the subject matter in question likely will be enhanced by the disclosure to a significant extent.

This final step in the "public interest" analysis requires an agency to focus as realistically as possible on the precise nature of the public contribution likely to result from a disclosure. It necessarily involves an assessment of the likely impact of the disclosure on the public's understanding of the subject in question, as compared to the level of public understanding of that subject existing prior to the disclosure. A differential analysis between the two should be undertaken in order to determine whether the contribution likely to result from the disclosure can be regarded as "significant."

The determination of "significance," which will require the exercise of especially careful judgment in many cases, is essentially an objective rather than a subjective determination. The agency's decision properly turns on whether the disclosure is likely to lead to a significant contribution to public understanding. This does not permit a separate value judgment by the agency as to whether the information, even though it in fact would contribute significantly to public understanding of the operations or activities of the government, is "important" enough to be made public.

If the agency determines that the likely contribution to public understanding is significant -- and each agency disclosing its own records under the FOIA is in the best position to evaluate the disclosable portions and reach such a judgment regarding their likely contribution to public understanding of government operations or activities -- then the fee waiver standard's "public interest" requirement is fully satisfied.

B. Disclosure of the Information "is Not Primarily in the Commercial Interest of the Requester."

Once an agency is satisfied that the first requirement for a fee waiver has been met, the statutory standard then requires a determination of whether disclosure of the requested information is primarily in the commercial interest of the requester; if it is, then a waiver is not warranted. To apply this second basic requirement, an agency must determine the magnitude of any commercial interest of the requester (or person upon whose behalf the requester may be acting) that would be furthered by disclosure, and then compare it to that of the public interest already identified.

(1) **The Existence and Magnitude of a Commercial Interest:** Whether the Requester has a Commercial Interest that Would be Furthered by the Requested Disclosure.

An agency must first determine as a threshold matter whether the request involves any commercial interest of the requester and, if so, assess the magnitude of that commercial interest. Only commercial interests that would be served by disclosure -- as opposed to other personal, non-commercial interests -- should be considered. A "commercial interest" is one that furthers a commercial, trade or profit interest as those terms are commonly understood. *See* OMB Fee Guidelines, sec. 6g. *Accord, e.g., American Airlines, Inc. v. National Mediation Board*, 588 F.2d 863, 870 (2d Cir. 1978) (defining "commercial" in Exemption 4 as meaning anything "pertaining or relating to or dealing with commerce"); *see also Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 644 F. Supp. 344, 346 (D.D.C. 1986) (entity's "non-profit status is not by itself determinative") (appeal pending). Thus, not only profit-making corporations but individuals or other organizations may have a commercial interest to be served by disclosure, depending upon the circumstances involved.

If the requester's interest in the records sought is unclear, it is entirely proper for agencies to consider and draw reasonable inferences from the requester's identity and the circumstances surrounding the request in determining the existence of a commercial interest. Where an agency reasonably believes that such circumstances suggest the existence of a commercial interest in disclosure, the requester should be given an opportunity in the administrative process to provide further information rebutting such reasonable inferences or clarifying the circumstances of the request where necessary. *Accord National Treasury Employees Union v. Griffin*, 811 F.2d at 647; *see also* OMB Fee Guidelines, sec. 6g.

Where a commercial interest is found to exist, and it would be furthered through the disclosure sought, the magnitude of that commercial interest must then be assessed. In making such an assessment, an agency should reasonably consider the role that such FOIA-disclosed information plays with respect to the requester's commercial interests, as well as the extent to which FOIA disclosures serve those interests overall.

(2) **The Primary Interest in Disclosure:** Whether the Magnitude of the Identified Commercial Interest of the Requester is Sufficiently Large, in Comparison with the Public Interest in Disclosure, that Disclosure is "Primarily in the Commercial Interest of the Requester."

Once a requester's commercial interest has been found to exist, the statute requires that an agency then determine whether disclosure of the information would be "primarily" in that interest. This requires the balancing of the requester's commercial interest against the public interest in disclosure that has been identified. Fundamentally, this balancing process is the same as that required under the previous fee waiver standard -- except that, once the more specific "public interest" standard is satisfied, the balance is now only between the magnitude of the public interest and the magnitude of requester's commercial interest, as those terms are used in the statute.

Where the "public interest" standard is satisfied as discussed above, and that public interest can fairly be regarded as greater in magnitude than the requester's commercial interest in disclosure, a fee waiver or reduction must be granted. Conversely, even where sufficient public interest exists to meet that more particular standard, a fee waiver is not warranted under the statute if the requester's commercial interest in disclosure is found to be greater than the public interest to be served, because disclosure would then be "primarily" in the requester's commercial interest.

Such comparisons, of course, require careful attention. For example, although newsgathering organizations usually have a commercial interest

in obtaining information, the traditional process of newsgathering and dissemination by established news media organizations, as a rule, should not be considered to be "primarily" in their commercial interest; because of their established role in providing information to the general public, it ordinarily can be presumed that, if a significant public interest has been identified, that will be the interest "primarily" served by disclosure to such organizations. On the other hand, the disclosure of agency records to data brokers or others who compile and market government information for direct economic return can more readily be considered as primarily in the commercial interests of the requester, depending on the nature of the records and the exact circumstances of the enterprise.

In the final analysis, each agency is best situated to make comparative assessments of the likely effects of disclosure of its own records; the statutory standard certainly affords agencies sufficient discretion with which to do so.

In making the subtle and sometimes difficult determinations required under the revised fee waiver standard, agencies should nevertheless strive to be as efficient as reasonably possible in expending agency resources on them. All fee waiver requesters, however, are entitled to full and careful consideration of the merits of their requests. (6) Where agencies undertake a fee waiver analysis according to the logical sequence of factors outlined in this guidance memorandum, they can confidently discharge their statutory obligations.

In addition to the foregoing guidance on the substantive factors to be considered in making fee waiver decisions, agencies should continue to refer to the procedural guidance with respect to fee waiver questions published in the January 1983 issue of *FOIA Update*, which remains effective. That guidance advises, for example, that agencies may grant a fee waiver in a percentage commensurate to the proportion of disclosable records that satisfy the statutory fee waiver standard. *See FOIA Update*, Jan. 1983, at 4.

Should any executive agency's administrative or legal personnel have any question regarding the implementation or interpretation of the new statutory fee waiver standard, they may contact the Department of Justice's Office of Information and Privacy, at (FTS) 633-3642 (633-FOIA).

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1. This guidance supersedes the previous fee waiver guidance issued by the Department of Justice in January 1983 and November 1986, and is effective with respect to fee waiver determinations made as of April 25, 1987. It interrelates in part with the OMB Fee Guidelines. Additionally, agencies considering fee waiver issues should note particularly the new specific fee limitation provisions to be found at 5 U.S.C. § 552(a)(4)(A)(ii), (iv), as amended, which are addressed in the OMB Fee Guidelines.

2. *United States v. Weber Aircraft Corp.*, 465 U.S. 792, 798 (1984) (FOIA decision applying statutory language on its face); *see also CIA v. Sims*, 471 U.S. 159, 167 (1985) (the "plain meaning" of such statutory terms should be applied). Decisions applying the language of the previous FOIA fee waiver standard are cited in this memorandum only where their holdings are consistent with the plain language of the revised standard.

Because of the accelerated procedures by which Congress enacted the Anti-Drug Abuse Act of 1986, of which the Freedom of Information

Reform Act was a part, at the close of the 99th Congress, there exists no committee report or actual floor debate on the revised fee provisions of the FOIA, although several prepared statements were inserted into the Congressional Record by Senators Hatch and Leahy and Congressmen English and Kindness. As regards the new statutory fee waiver standard, its plain meaning may readily be determined from its language.

3. The 1986 amendments to the FOIA added a new clause (vi) providing that "Nothing in this subparagraph [containing the FOIA's fee provisions] shall supersede fees chargeable under a statute specifically providing for setting the level of fees for particular types of records." 5 U.S.C. § 552(a)(4)(A)(vi). Accordingly, this guidance does not apply to fee waivers sought in connection with requests for Defense Department technical data that are subject to the separate statutory fee and fee waiver scheme to be codified at 10 U.S.C. § 2328. It also does not apply to fees assessed or fee waivers sought in connection with requests for information provided by the National Technical Information Service, *see* 15 U.S.C. § 1153 (1982), or in connection with a request for records under any other statute providing for the separate charging of fees within the meaning of this provision. *See* OMB Fee Guidelines, sec. 6b. Fees and, if applicable, fee waivers for such records should be determined according to the standards provided in those statutes, not according to the FOIA.

4. By its terms, the revised fee waiver standard provides that the two statutory requirements it contains must be met before the requester is entitled to a waiver or reduction of fees. It does not, however, automatically require a complete waiver of all fees whenever those requirements are met; § 552(a)(4)(A)(iii) instead provides that "[d]ocuments shall be furnished without any charge or at a charge reduced below the [otherwise applicable] fees" if both requirements of the fee waiver standard are met.

As a matter of course, the Department of Justice encourages agencies to provide a waiver of fees when both requirements of the statutory standard are met, just as they must deny a waiver of fees whenever one or both of those requirements are not met.

However, Congress in amending the FOIA specifically revised and retained the reduction language in the fee waiver standard, and that language should be read to have some effect. *Accord United States v. Menasche*, 348 U.S. 528, 538-39 (1955) (court has duty to give effect, if possible, to every clause and word of statute); *see also Jarecki v. G.D. Searle & Co.*, 367 U.S. 303, 307 (1961). Therefore, in rare cases, perhaps involving exceptional burden or expenditure of public resources in the context of a request that minimally satisfies the "public interest" requirement, it may be possible to give effect to the language of the statute providing for "a charge reduced below the [otherwise applicable] fees" by granting a reduction rather than a complete waiver of fees.

5. The term "representative of the news media" appears in 5 U.S.C. § 552(a)(4)(A)(ii), which precludes the charging of search fees to certain categories of requesters. Though that term does not appear in the fee waiver standard of the Act, § 552(a)(4)(A)(iii), the fact that a request is from a "representative of the news media" for purposes of clause (ii) is clearly a relevant factor in evaluating a waiver or reduction of duplication charges under the fee waiver standard of clause (iii).

6. Decisions on fee waiver requests are matters committed to the exercise of sound agency discretion in the first instance. Once a fee waiver issue proceeds to court, however, a new judicial review provision included in the amended FOIA, 5 U.S.C. § 552(a)(4)(A)(vii), provides for review of agency fee waiver denials according to a *de novo* standard, as opposed to the more deferential "arbitrary or capricious" standard

previously employed.

The scope of judicial review of fee waiver determinations, however, remains limited to the administrative record established before the agency. *Id.* As a general rule of administrative law, this record ordinarily cannot be supplemented in litigation either by the agency or by the requester. *See, e.g., National Treasury Employees Union v. Griffin*, 811 F.2d at 648. It therefore is imperative that an agency create a comprehensive administrative record of each fee waiver denial, specifying in as much detail as reasonably possible each of the grounds upon which it is based. *See FOIA Update*, Winter 1985, at 6.

It should be noted, however, that the *de novo* review standard of § 552(a)(4)(A)(vii) applies by its terms only to the "waiver of fees," *i.e.*, to determinations made under clause (iii). Thus, agency determinations of fee assessments made under any other provision of § 552(a)(4)(A) should continue to be subject to judicial review according to the traditional "arbitrary or capricious" standard.

Go to: FOIA Update Home Page

Exhibit Q

DERMABOND adhesive

DERMABOND adhesive, which is used to replace sutures, staples and adhesive strips for closing certain topical incisions and lacerations, is the first such product to be approved by the FDA for the U.S. market. Ethicon, Inc. ("Ethicon"), a subsidiary of Johnson & Johnson, was licensed exclusive worldwide marketing and distribution rights for DERMABOND adhesive which is currently marketed in the U.S. and approximately 35 countries outside the U.S., including Japan. In the first quarter of 2001, the Company released its first DERMABOND adhesive line extension which utilizes a "chisel tip" configuration allowing

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for a fine-line application as compared to the broad-line application of the original "dome tip". In the third quarter of 2001, the Company shipped its second DERMABOND adhesive line extension, an increased viscosity formulation ("HVD"), to Ethicon for distribution internationally. Upon approval from the FDA of the Company's recently filed premarket approval ("PMA") supplement, HVD will be available for distribution in the U.S. The Company has also submitted a PMA supplement to expand the DERMABOND device labeling to include a microbial barrier claim as it relates to preventing postoperative contamination of wounds. The Company has already added the microbial barrier claim to labeling for product distributed internationally.

In July 1999, the Company was awarded its first United States Patent related to DERMABOND adhesive. The invention covered

Exhibit Q

Exhibit R

Medicare
Carriers Manual
Part 3 - Claims Process

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Transmittal 1704 **Date: MAY 25, 2001**

These manual sections incorporate instructions previously issued in a memorandum to HCFA Associate Regional Administrators in August of 1996 on Medicare Coverage of and Processing of Claims for Investigational Devices. This action is merely a manualization of these instructions. Coverage of certain investigational devices became effective on November 1, 1995.

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
Table of Contents - Chapter II	2-3 - 2-6 (4 pp.)	2-3 - 2-6 (4 pp.)
2301.1	----	2-109.2 - 2-109.3 (2 pp.)
2484	2-153 - 2-158	----
Table of Contents - Chapter III	3-1.2 - 3-2 (2 pp.)	3-1.2 - 3-2 (2 pp.)
3313 - 3319	3-85 - 3-85.2 (3 pp.)	3-85 - 3-86 (2 pp.)
Table of Contents - Chapter IV	4-1 - 4-2 (2 pp.)	4-1 - 4-2 (2 pp.)
4121.3 - 4130	4-38.1 - 4.38.3 (3 pp.)	4-38.1 (1 p.)

MANUALIZATION--***EFFECTIVE DATE: Not Applicable***
IMPLEMENTATION DATE: Not Applicable

Section 2303.1, Devices Not Approved by FDA, has been **deleted**.

Section 2484, Coverage Of Medical Devices Under Medicare, outlines coverage of medical devices under Medicare coverage of certain FDA-approved investigational device exemption (IDE) devices and the services related to these devices. It describes the conditions and limits of coverage and payment for specified devices with an FDA approved IDE.

Section 3317, Appeals Process for IDE Categorization Decisions, specifies the procedure that a sponsor (typically, the manufacturer) must follow if the sponsor does not agree with the FDA categorization of its device.

Section 4122, Certain Devices with a Food and Drug Administration (FDA) Investigational Device Exemption (IDE), explains payment and billing procedures and defines devices in HCFA's Master Investigational Device file.

Section 4122.1, Certain Devices with an FDA Investigational Device Exemption, describes the procedures to be used for processing payment of claims for investigational devices.

Section 4122.2, Payment of Certain Investigational Devices, explains the new benefit provided as a result of the revised coverage policy for investigational devices.

Exhibit R

D. Coverage Requirements.--Medicare contractors are responsible for making the coverage determinations on all FDA-approved Category B devices. Coverage decisions should be made for FDA-approved investigational device exemptions (IDEs), as they currently are made for FDA-approved devices, i.e., apply Medicare's long-standing criteria and procedures for making coverage decisions. The following criteria must also be applied when making coverage determinations on FDA-approved IDE Category B devices:

? The device must be used within the context of the FDA-approved clinical trial.

? The device must be used according to the clinical trial's approved patient protocols.

? Established national policy as contained in existing manual instructions, e.g., Coverage Issues Manual instructions, etc.

? In the absence of national policy, local policy for similar FDA-approved devices.

? Policy/Position papers or recommendations made by pertinent national and/or local specialty societies.

Contractors should also consider, among other factors, whether the device is:

1. Medically necessary for the particular patient and whether the amount, duration and frequency of use or application of the service are medically appropriate and,

2. Furnished in a setting appropriate to the patient's medical needs and condition.

This policy does not provide coverage for any devices that would otherwise not be covered by Medicare; e.g., statutorily excluded devices or items and services excluded from coverage through regulation or current manual instructions.

E. Hospital Institutional Review Board (IRB) Approved IDE Devices.--Clinical trials for non-significant risk devices (devices which do not require an FDA-approved IDE are the responsibility of the hospital's IRB. While these devices do not require an FDA-approved IDE, many of the FDA-approved IDE requirements apply to these nonsignificant risk devices (e.g., they may not be legally marketed). Medicare contractors are responsible for making the coverage determinations on nonsignificant devices that are the responsibility of the hospital's IRB. Contractors should apply the same coverage criteria, where appropriate to these devices as is applied to FDA-approved IDE Category B devices.

F. Payment for IDE Category B Devices.--Payment for a Category B IDE device or an IRB approved device (provided to a nonhospital patient) and related services is limited to or less than what Medicare would have paid for a comparable approved device or services.

G. Services Related to and Required as a Result of Services Which are Not Covered Under Medicare.--This policy does not affect Medicare's coverage of services related to a noncovered device. That is, services related the use of a noncovered device are not covered under Medicare.

H. FDA Withdrawal of IDE Approval.--Potential Medicare coverage of Category B IDE devices is predicated, in part, upon their status with the FDA. In the event a sponsor (e.g., a manufacturer) loses its Category B status, or violates relevant IDE requirements necessitating FDA's withdrawal of IDE approval, all payment of the device should cease. Carriers should inform the provider community that billing for the IDE means that the provider attests that the study was approved at the time the service was rendered. The HCFA master file will be updated to reflect withdrawals of FDA IDE approvals.

Dear Ms. Brown:

The Food and Drug Administration (FDA) has received your investigational device exemption (IDE) application. Your application is conditionally approved, and you may begin your investigation, using a revised informed consent document which corrects deficiency numbers one and two in accordance with the investigational site waiver granted below. Your investigation is limited to a feasibility study at three of the institutions listed in your submission and ten subjects.

This approval is being granted on the condition that, within 45 days from the date of this letter, you must submit information correcting the following deficiencies:

1. Per 21 CFR 812.5(b), this manufacturer of the IDE shall not represent that the device is effective for the purpose for which is being investigated. Please revise the informed consent form in conformance with the following:

? Remove the statement that the device is in use in over 10,000 patients.

? Remove paragraph two under purpose of the study.

? Remove the statement regarding pregnant women.

? Remove the statement under anticipated benefits of the study that says, From the experiences of patients who have received it in other countries.

This information should be identified as an IDE supplement referencing the IDE number above and must be submitted in triplicate to_____.

If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application. The FDA will waive those requirements regarding the submission and prior FDA approval of a supplemental application and receipt of certification of institutional review board (IRB) approval for the addition of investigational sites (21 CFR 812.45(b) provided:

1. The total number of investigational sites does not exceed three.

2. You maintain current records on:

? The names and addresses of all investigational sites:

? The names and addresses of all investigators, identifying those that are currently participating:

? The names, addresses and chairpersons of all IRBs;

? The dates of the IRB approvals; and,

? The dates of first shipment or first use of investigational devices for all participating institutions.

If you agree to these conditions, you may begin an investigation at a new investigational site after the IRB has approved the investigation. No documentation should be submitted for any institution within the approval limit until the investigational site limit is reached or the 6-month current investigator list is due. The FDA assumes that you have agreed to the conditions of this waiver unless you specifically notify us in writing of your disagreement.

Please note, however, that you must submit a letter to expand the investigation beyond the limit specified above. Additionally, if you do not agree to these conditions, you must comply with the full requirements for the submission to the FDA of a supplemental IDE application for new investigational sites not already specifically approved for participating in your study (21 CFR 812.35 (b)).

We would like to point out that the FDA approval of your IDE application does not imply that this investigation will develop sufficient safety and effectiveness data to assure FDA approval of a pre-market approval (PMA) application for this device. You may obtain the guideline for the preparation of a PMA application, entitled Pre-market Approval (PMA) Manual, from the Division of Small Manufactures Assistance at its toll free number.

We have enclosed the guidance document entitled, Sponsor's Responsibilities for a Significant Risk Device Investigation to help you understand the functions and duties of a manufacturer. Also enclosed is the guidance document entitled Investigators Responsibilities for a Significant Risk Device Investigation which you should provide to participating investigators.

If you have any questions, please contact _____.

Sincerely yours,

3314. PHYSICIAN OR SUPPLIER REFUSES TO SUBMIT MEDICARE CLAIMS

Section 1848(g)(4) of the Social Security Act requires all physicians and suppliers to submit Part B claims processed by Medicare carriers for covered services furnished to program beneficiaries on or after September 1, 1990. Those physicians and suppliers who knowingly, willfully and repeatedly fail to submit a claim are subject to sanctions, including civil monetary penalties of up to $2000 per violation and exclusion from the Medicare program. OIG is responsible for assessing sanctions.

A beneficiary complaint to you, SSA, or HCFA may occur where a physician or supplier fails to adhere to the claim submission requirement. This may happen, for example, when a beneficiary submits a HCFA-1490S claim and your EOMB notice indicates that the physician or supplier should have filed the claim. The beneficiary may indicate that the physician or supplier refused to comply.

Develop such complaints received and make physician or supplier educational contacts, as appropriate. If physician or supplier noncompliance is not corrected (i.e., your monitoring program consistently identifies a service provider as having 11 or more potential violations per month and educational contacts do not resolve the problem), establish controls to develop and refer cases to OIG after the 12 month filing limit is exceeded. (See §7560.)

3316. PHYSICAL EXAMINATIONS OF BENEFICIARIES BY CARRIERS

You have the authority to obtain an independent medical examination of a beneficiary where your medical personnel conclude that such an examination will assist in properly and effectively complying with your responsibilities. Expenses incurred in connection with obtaining such independent medical examinations are payable administrative costs. It is expected, however, that carrier-initiated examinations will be utilized only after other methods of resolving the issue have been explored and found to be insufficient, and then, only with the express permission of the beneficiary. (Information which may be derived from hospital records and contacts with the beneficiary's attending physician and evaluations of such data by your medical personnel, as well as the appropriate committees of local medical societies, are among the more usual methods available to resolve questionable claims before initiating an examination of the beneficiary.) The only use to make of the medical information derived from an independent examination is to assist you in the claims review process.

3317. APPEALS PROCESS FOR INVESTIGATIONAL DEVICE EXEMPTION (IDE) CATEGORIZATION DECISIONS

The Food and Drug Administration (FDA) assigns an IDE number that corresponds to each IDE application received. Through an interagency agreement HCFA and the FDA have developed a process to categorize all FDA-approved IDEs for Medicare coverage and payment purposes. This categorization process differentiates between novel, first-of-a-kind devices for which absolute risk of the device has not been established (Category A), and those devices which are of a device type for which the underlying questions of safety and effectiveness have been resolved (Category B). (See §2484).

Any manufacturer that does not agree with the FDA decision that categorizes its device as Category A-experimental may submit a written request asking the FDA to reevaluate its categorization decision. The sponsor (e.g., a manufacturer) may send a written request to the FDA at any time asking for a reevaluation of its original categorization decision, submitting any additional evidence and information which it believes supports a recategorization. The FDA notifies both HCFA and the sponsor (manufacturer) of its re-evaluation decision.

CHAPTER IV
CLAIMS REVIEW AND ADJUDICATION PROCEDURES

4121.3 Denial Messages.--When you deny the claim, use the following messages:

A. MSN/EOMB.--

21.22/16.58 "Medicare does not pay for this service because it is considered investigational and/or experimental in these circumstances."

B. Remittance Advice.--American National Standard Institute (ANSI) X-12-835 claim adjustment reason code/message B22, "This claim/service is denied/reduced based on the diagnosis."

4122 CERTAIN DEVICES WITH A FOOD AND DRUG ADMINISTRATION (FDA) INVESTIGATIONAL DEVICE EXEMPTION (IDE)

4122.1 Payment for Certain Investigational Devices.--For dates of service on or after November 1, 1995, Medicare may cover certain FDA-approved and Institutional Review Board (IRB) approved investigational devices and services incident to, provided the investigational device meets the following conditions:

? Appears on the listing of devices eligible for coverage/payment on HCFA's master file of IDE devices (See §4122.3)

? Is reasonable and necessary for the individual patient;

? The device or services associated with the use of a device were provided to the beneficiary within the start and end dates contained in the master file.

? There is no national coverage policy that would otherwise prohibit Medicare coverage.

(See §2484 of the Medicare Carriers Manual for additional coverage instructions for FDA-approved investigational devices.)

4122.2 Billing Requirements for FDA-Approved Investigational Devices.--Providers bill using the appropriate HCPCS code. Instruct billers to identify claims for investigational devices and/or services incident to the use of such devices with the "QA" modifier. Item 23 of the HCFA-1500 is used by billers to enter the investigational device exemption number assigned to the device. For electronic claims, the device number is entered in the DAO field of the national standard format field 14. The ANSI 837 is position 180 Ref segment, REF 01 value of LX and REF 02 for the investigational device exemption number. (Providers must obtain the investigation device exemption number from the manufacturer supplying the device in the clinical trial.) Providers may also provide a copy of their approval letter (See §2030 C and I. Also see §4122.4B) to substantiate their claim for payment, though this is not mandatory.

4122.3 HCFA's Master File of Investigational Devices.--The devices in the master file are only those devices that may be covered if they meet the coverage criteria outlined in §2030 of the Medicare Carriers Manual. Carriers may access HCFA's master file of investigational devices through the network data mover. The file will be updated as appropriate.

HCFA's master file of investigational devices contains the following fields:

? The investigational device exemption (IDE) number.
? HCPCS code(s) (where available).
? Narrative description of the device.
? Start date.
? End date.
? Maintenance date.

Listed below is a brief description of the fields contained in the HCFA's master file of investigational devices.

Investigational Device Exemption Number - The investigational device exemption number is an alphanumeric (one alpha and six numeric) character that is assigned by the FDA to an investigational device and must be used when filing a claim.

HCPCS Codes - HCFA has identified (where possible) HCPCS code(s) that providers may use to bill for these investigational devices. In the master file of investigational devices some have no identified HCPCS code associated with the claim; these may be billed using the appropriate miscellaneous HCPCS code. Carriers are not to deny claims just because they may have HCPCS code(s) other than those in the master file.

HCFA's master file of investigational devices is to be used as a guide. The indications of use for the device shall be used to determine the appropriate HCPCS code. When you identify additional HCPCS Code(s) for billing the investigational device, notify HCFA (See §4122.2).

Narrative Description - HCFA has provided a brief description of the investigational device, e.g., intraocular lens. This information should assist you in identifying whether the provider is billing correctly.

Start Date - The start date field houses the beginning of the approval period for that investigational device. Claims received with dates of service prior to this date should be denied (See§4122.4 B for the appropriate EOMB message).

End Date - The end date field indicates the completion of the clinical trial for that device. Claims received with dates of service after that date should be denied (See §4122.5 for the appropriate EOMB message).

Maintenance Date -- This is an optional field. It may indicate the date on which a field pertaining to an IDE record is changed.

4122.4 Adjudicating the Claim.--

A. FDA Approval.--Investigational devices are only covered when they are used in a clinical trial approval by the FDA. When billing a service with the investigational modifier, the provider is certifying FDA approval of a clinical trial for the device.

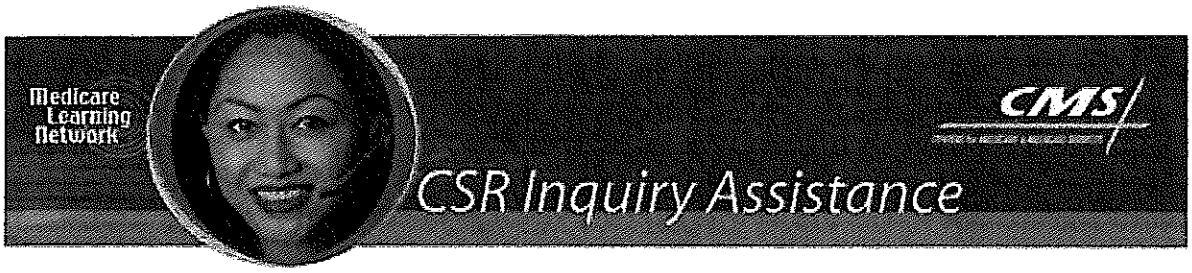
B. Editing the Claim Against the Master File of Investigational Devices.--Claims for investigational devices should be edited against the master file. **Deny** claims in instances where the investigation device exemption number is not found in the master file. When providers submit documentation that a device is a Category B device, carriers should confirm this information with HCFA (E-mail destination SHIPPLER or fax (410) 786-6730). Only after an updated master file is received that contains the investigational device exemption number in question is the claim to be processed.

4122.5 MSN/EOMB Messages.--Providers must identify services for an investigational device and/or the services incident to such devices using a two-digit procedure code modifier as specified in §4122.2.

Deny claims for investigational devices that are Category A devices, using the following EOMB message when denying the assigned claim:

"Medicare does not pay for this investigational device(s)."

Exhibit S



Related MLN Matters Article #: MM3604

Date Posted: March 17, 2005

Related CR #: 3604

Billing for Implantable Automatic Defibrillators for Beneficiaries in a Medicare Advantage (MA) Plan and Use of the QR Modifier to Identify Patient Registry Participation

Key Words

Implantable, Defibrillators, MA, QR, CR3604, MM3604, Payment, CR2880, CR2992, CR3301, MM3301, R497CP, FSS, 427.1, 427.2, 427.5, 427.9, IDE

Provider Types Affected

All Medicare providers billing either a Medicare carrier or fiscal intermediary (FI) for Implantable Automatic Defibrillators for Medicare beneficiaries who are members of Medicare Advantage plans

Key Points

- The effective date of the instruction is January 27, 2005.
- The implementation date is January 27, 2005.
- The implementation date for the QR modifier is April 4, 2005.
- The national coverage for implantable automatic defibrillators is being expanded to include the following new indications:
  - Patients with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction (LVEF) ≤ 35%;
  - Patients with nonischemic dilated cardiomyopathy (NIDCM) > 9 months, NYHA Class II and III heart failure, and measured LVEF ≤ 35%;
  - Patients who meet all current CMS coverage requirements for a cardiac resynchronization therapy (CRT) device and have NYHA Class IV heart failure;
  - Patients with NIDCM > 3 months, NYHA Class II or III heart failure, and measured LVEF ≤ 35%.
- Defibrillator use for these new indications is not part of the capitated rates and is to be paid Fee-For-Service (FFS) when the beneficiary is under a MA plan.

- Payment for previously covered indications for defibrillator use, i.e., those indications approved prior to January 27, 2005, will be part of the MA capitated rates and are not to be paid on a FFS basis for beneficiaries under a MA plan.
- Data must be collected and reported through an approved data collection mechanism for beneficiaries that receive an implantable automatic defibrillator for the primary prevention of sudden cardiac death.
- The following is a summary of the history of indications for implantable defibrillators leading up to CR3604:
  - **July 1, 1991** - Documented episode of cardiac arrest due to Ventricular Fibrillation (VF), not due to a transient or reversible cause;
  - **July 1, 1999** - Documented sustained Ventricular Tachyarrhythmia (VT), either spontaneous or induced by an Electrophysiology (EP) study, not associated with an acute Myocardial Infarction (MI) and not due to a transient or reversible cause; Documented familial or inherited conditions with a high risk of life-threatening VT, such as long QT syndrome or hypertrophic cardiomyopathy;
  - **October 1, 2003** - Coverage was expanded to include coronary artery disease with a documented prior MI, a measured left ventricular ejection fraction ≤ 0.35, and inducible, sustained VT or VF at EP study. (The MI must have occurred more than 4 weeks prior to defibrillator insertion. The EP test must be performed more than 4 weeks after the qualifying MI.)
- The following summarize the history of payment policies for implantable defibrillators leading up to CR 3604:
  - **October 1, 2003 (CRs 2880 & 2992)** - For covered defibrillator claims made on behalf of MA (formerly known as M+C) beneficiaries, payment for the expanded coverage (above) would be made on a FFS basis until Medicare capitation rates to MA organizations were adjusted to account for expanded coverage.

    System changes were implemented to enable the automatic processing and payment of covered defibrillator claims on a FFS basis when the beneficiary was under a MA plan and the claims included either a KZ modifier attached to the defibrillator procedure codes when billing a carrier or a condition code of 78 when billing a fiscal intermediary.
  - **January 1, 2005 (CR 3301)** - Because MA rates have been appropriately adjusted to account for the defibrillator coverage described in CRs 2880 and 2992, covered services for the indications in these CRs will no longer be paid FFS when the beneficiary is under a MA plan.
  - **January 27, 2005 (CR 3604)** - CMS announces expanded coverage for implantable defibrillators for additional indications, as previously indicated.
- Providers should include a KZ modifier for carrier claims and a condition code of 78 for fiscal intermediary claims until the MA capitated rates are adjusted to indicate that the beneficiary is under an MA plan and the services provided are for one of the new indications.
- MA plan beneficiaries are responsible for paying applicable coinsurance, but are not responsible for paying Part A or Part B deductibles (so providers should assume that the Part A or Part B deductible has been met).

- For indications effective after January 27, 2005, patients must not have:
  - Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
  - Had a coronary artery bypass graft (CABG) or Percutaneous Transluminal Coronary Angioplasty (PTCA) within the past 3 months;
  - Had an acute MI within the past 40 days;
  - Clinical symptoms or findings that would make them a candidate for coronary revascularization; or
  - Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than one year.
- All patients considered for implantation of a defibrillator must be able to give informed consent.
- Myocardial infarctions must be documented and defined according to the consensus document of the Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction.
- Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography.
- Providers must be able to justify the medical necessity of devices other than single lead devices.
- This justification should be available in the medical record.
- Patients receiving a defibrillator for the new indications (or for any other indication that is for the primary prevention of sudden cardiac arrest [no history of a previous cardiac arrest]) must be enrolled in either a Food and Drug Administration-approved Category B Investigational Device Exemption (IDE) clinical trial, a trial under the Centers for Medicare & Medicaid Services Clinical Trial Policy, or a qualifying data collection system including approved clinical trials and registries to ensure the safety and quality of care.
- CMS will maintain an implantable automatic defibrillator registry using a mechanism that Medicare participating hospitals already use to submit quality data to the Quality Improvement Organizations (QIOs).
- Hospital staff will fill out the data collection form (supplied by CMS) using the ICD Abstraction Tool and transmit it via QNet (Quality Network Exchange) to the QIO.
- Iowa Foundation for Medical Care (IFMC) will collect and maintain registry data and the QIOs will be able to ensure the quality of the data by sampling charts.
- Additional information on the ICD Abstraction Tool is available through a previously issued Special Edition MLN Article (SE0517).
- The QR modifier was created for use on Part B claims to identify protocol covered services.
- The appropriate use of the QR modifier, in defibrillator claims, is to identify patients whose data is being submitted to a registry and to document meeting the coverage requirement for devices implanted for primary prevention of sudden cardiac arrest.
- Providers should only append the QR modifier on claims submitted on or after April 1, 2005.

- This modifier is not required when ICD-9-CM codes 427.1 ventricular tachycardia; 427.41 ventricular fibrillation; 427.42 ventricular flutter; 427.5 cardiac arrest; 427.9 cardiac dysrhythmia, unspecified appear on the claim, as these codes identify a patient receiving the device as secondary, not primary prevention, of sudden cardiac arrest.
- If none of the above ICD-9 diagnosis codes applies to the device implant, patient data should be submitted to a registry and the QR modifier is required for claims submitted on or after April 1, 2005.
- Providers billing **Medicare FIs** should:
  - Use the following G codes (payable under OPPS effective October 1, 2003): G0297, G0298, G0299, and G0300;
  - Use the following ICD-9-CM procedure code on 11X type of bills: 37.94.
- Providers billing **carriers** should use procedure code 33249.

Important Links

http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3604.pdf

http://www.cms.hhs.gov/transmittals/downloads/R497CP.pdf

http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3301.pdf

http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0517.pdf

Medicare Learning Network
Medlearn Matters
Information for Medicare Providers
CMS

Related Change Request (CR) #: 3604
Related CR Release Date: March 4, 2005
Related CR Transmittal #: 488
Effective Date: January 27, 2005
Implementation Date: January 27, 2005
Implementation Date for QR Modifier: April 4, 2005

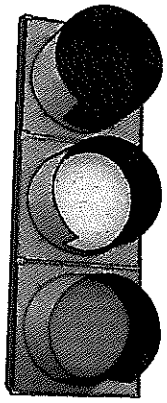
Medlearn Matters Number: MM3604

Billing for Implantable Automatic Defibrillators for Beneficiaries in a Medicare Advantage (MA) Plan and Use of the QR Modifier to Identify Patient Registry Participation

Provider Types Affected

All Medicare providers billing either a Medicare carrier or Fiscal Intermediary (FI) for Implantable Automatic Defibrillators for Medicare beneficiaries who are members of Medicare Advantage plans

Provider Action Needed



STOP – Impact to You

Be aware that CMS is expanding the set of medical indications for the use of implantable automatic defibrillators and this instruction discusses the impact of this change for beneficiaries who are members of a MA plan and receive these services.

Effective January 27, 2005, CMS is expanding national coverage for implantable automatic defibrillators by including the following new indications:

1. Patients with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction (LVEF) ≤ 35%;
2. Patients with nonischemic dilated cardiomyopathy (NIDCM) > 9 months, NYHA Class II and III heart failure, and measured LVEF ≤ 35%;
3. Patients who meet all current CMS coverage requirements for a cardiac resynchronization therapy (CRT) device and have NYHA Class IV heart failure;
4. Patients with NIDCM > 3 months, NYHA Class II or III heart failure, and measured LVEF ≤ 35%.

(See Note below)

GO – What You Need to Do

Make sure that your billing staffs are aware of these new indications and also the basis for billing Medicare.

Note: For beneficiaries under a MA plan, payment for defibrillator use effective January 27, 2005, is different for these new indications than it is for previously covered indications. When the beneficiary is under a MA plan, defibrillator use for these new indications is not part of the capitated rates and is to be paid Fee-For Service (FFS). However, payment for previously covered indications for defibrillators implanted in these beneficiaries will be part of the MA capitated rates and is not to be paid FFS. In addition, data must be collected and reported through an approved data collection mechanism for beneficiaries that receive an implantable automatic defibrillator for the primary prevention (as opposed to secondary prevention) of sudden cardiac death. The above indications are considered primary prevention indications. Additional information regarding the ICD Abstraction Tool is available through a previously issued Special Edition MedLearn Article (SE0517) which is available at:
http://www.cms.hhs.gov/medlearn/matters/mmarticles/2005/SE0517.pdf

Background

The Implantable Automatic Defibrillator, consisting of a pulse generator and electrodes for sensing and defibrillating, is an electronic device designed to detect and treat life-threatening tachyarrhythmias. Medicare pays for the use of these defibrillators for only certain clinical indications.

Here is a synopsis of the history of indications and payment policies (indicating the effective dates) for implantable defibrillators, leading up to Change Request (CR) 3604:

Indications

- July 1, 1991

Documented episode of cardiac arrest due to Ventricular Fibrillation (VF), not due to a transient or reversible cause

- July 1, 1999

Documented sustained Ventricular Tachyarrhythmia (VT), either spontaneous or induced by an Electrophysiology (EP) study, not associated with an acute Myocardial Infarction (MI) and not due to a transient or reversible cause

Documented familial or inherited conditions with a high risk of life-threatening VT, such as long QT syndrome or hypertrophic cardiomyopathy

- October 1, 2003

Coverage was expanded to include coronary artery disease with a documented prior MI, a measured left ventricular ejection fraction ≤ 0.35, and inducible, sustained VT or VF at EP study. (The MI must have occurred more than 4 weeks prior to defibrillator insertion. The EP test must be performed more than 4 weeks after the qualifying MI).

Payment Policies

- October 1, 2003 (CRs 2880 & 2992)

For covered defibrillator claims made on behalf of MA (formerly known as M+C) beneficiaries, payment for the expanded coverage (above) would be made on a FFS basis until Medicare capitation rates to MA organizations were adjusted to account for expanded coverage.

Also at this time, system changes were implemented to enable the automatic processing and payment of covered defibrillator claims on a FFS basis when the beneficiary was under a MA plan and the claims included either a KZ modifier attached to the defibrillator procedure codes when billing a carrier or a condition code of 78 when billing a fiscal intermediary.

- January 1, 2005 (CR 3301)

Because MA rates have been appropriately adjusted to account for the defibrillator coverage described in CRs 2880 and 2992, covered services for the indications in these CRs will no longer be paid FFS when the beneficiary is under a MA plan.

Now in CR 3604, Medicare announces expanded coverage for implantable defibrillators for additional indications, effective January 27, 2005. These indications are:

- Patients with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction (LVEF) ≤ 35%;
- Patients with nonischemic dilated cardiomyopathy (NIDCM) > 9 months, NYHA Class II and III heart failure, and measured LVEF ≤ 35%;
- Patients who meet all current CMS coverage requirements for a cardiac resynchronization therapy (CRT) device and have NYHA Class IV heart failure;
- Patients with NIDCM > 3 months, NYHA Class II or III heart failure, and measured LVEF ≤ 35%.

Please note this additional information:

- Since this new coverage exceeds the significant cost threshold for managed care organizations, services related to the newly covered indications will be paid only on a fee-for-service basis for patients enrolled in a managed care plan. To reiterate, for these new indications, Medicare will pay for covered defibrillators on a FFS basis for claims for beneficiaries under MA plans through December 31, 2005. (Coverage guidelines can be found in the National Coverage Determination Manual (NCDM), Section 20.4.). **As a reminder, remember that MA plan beneficiaries are responsible for paying applicable coinsurance, but are not responsible for paying Part A or Part B deductibles (so you should assume that the Part A or Part B deductible has been met). To indicate that the beneficiary is under an MA plan and the services provided are for one of the new indications, providers are to include a KZ modifier for carrier claims and a condition code of 78 for fiscal intermediary claims until the MA capitated rates are adjusted.**

- Payment for previously covered indications for defibrillator use, i.e., those indications approved prior to January 27, 2005, will be part of the MA capitated rates and are not to be paid on a FFS basis for beneficiaries under a MA plan.
- Except for reimbursing for the use of the defibrillators for the new indications, the processing of defibrillator claims for non-MA beneficiaries remains unchanged.
- For indications effective after January 27, 2005, patients must not have:
  - Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
  - Had a coronary artery bypass graft (CABG) or Percutaneous Transluminal Coronary Angioplasty (PTCA) within the past 3 months;
  - Had an acute MI within the past 40 days;
  - Clinical symptoms or findings that would make them a candidate for coronary revascularization; or
  - Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year.
- All patients considered for implantation of a defibrillator must be able to give informed consent.
- Myocardial infarctions must be documented and defined according to the consensus document of the Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction.
- Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography.
- Providers must be able to justify the medical necessity of devices other than single lead devices. This justification should be available in the medical record.

You should also be aware that Medicare is requiring that patients receiving a defibrillator for the new indications (or for any other indication that is for the primary prevention of sudden cardiac arrest [no history of a previous cardiac arrest]) be enrolled in either a Food and Drug Administration-approved Category B Investigational Device Exemption (IDE) clinical trial, a trial under the Centers for Medicare & Medicaid Services Clinical Trial Policy, or a qualifying data collection system including approved clinical trials and registries to ensure the safety and quality of care.

Initially, CMS will maintain an implantable automatic defibrillator registry using a mechanism that Medicare participating hospitals already use to submit quality data to the Quality Improvement Organizations (QIOs). Hospital staff will fill out the data collection form (supplied by CMS) using the ICD Abstraction Tool and transmit it via QNet (Quality Network Exchange) to the QIO. Iowa Foundation for Medical Care (IFMC) will collect and maintain registry data and the QIOs will be able to ensure the quality of the data by sampling charts. Additional information regarding the ICD Abstraction Tool is available through a previously issued Special Edition MedLearn Article (SE0517), which is available at:

http://www.cms.hhs.gov/medlearn/matters/mmarticles/2005/SE0517.pdf

Additional data collection systems (trials or registries) addressing at a minimum the hypotheses specified in this decision must meet the following basic criteria:

- Written protocol on file;
- Institutional Review Board review and approval;
- Scientific review and approval by two or more qualified individuals who are not part of the research team;
- Certification that investigators have not been disqualified.

For purposes of this coverage decision, CMS will determine whether specific registries or clinical trials meet these criteria.

Also, remember that the QR modifier was created for use on Part B claims to identify protocol covered services. The appropriate use of the QR modifier, in defibrillator claims, is to identify patients whose data is being submitted to a registry and to document meeting the coverage requirement for devices implanted for primary prevention of sudden cardiac arrest. Providers should only append the QR modifier on claims submitted on or after April 1, 2005. This modifier is not required when ICD-9-CM codes 427.1 ventricular tachycardia; 427.41 ventricular fibrillation; 427.42 ventricular flutter; 427.5 cardiac arrest; 427.9 cardiac dysrhythmia, unspecified appear on the claim, as these codes identify a patient receiving the device as secondary, not primary prevention, of sudden cardiac arrest.

On the other hand, if none of the above ICD-9 diagnosis codes applies to the device implant, patient data should be submitted to a registry and the QR modifier is required for claims submitted on or after April 1, 2005.

One final note:

- Providers billing Medicare Fiscal Intermediaries (FIs) should:
  - Use the following G codes (payable under OPPS effective October 1, 2003): G0297, G0298, G0299, and G0300.

    Note: These G codes are not payable under the Medicare Physician Fee Schedule and, therefore, should not be billed to Medicare carriers.
  - Use the following ICD-9-CM procedure code on 11X type of bills: 37.94
- Providers billing carriers should use procedure code 33249.

Additional Information

You can find more information about Billing for Implantable Automatic Defibrillators for Beneficiaries in a MA Plan by going to:

http://www.cms.hhs.gov/manuals/transmittals/comm_date_dsc.asp

From that web page, look for CR 3604 in the CR NUM column on the right, and click on the file for that CR.

Finally, if you have any questions, please contact your carrier/intermediary at their toll-free number, which may be found at:

http://www.cms.hhs.gov/medlearn/tollnums.asp

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF INSPECTOR GENERAL

Office of Audit Services
Region I
John F. Kennedy Federal Building
Room 2425
Boston, MA 02203
(617) 565-2684

JAN 31 2002

CIN: A-01-01-00550

Mr. Stephen Abbott
President and Chief Executive Officer
Cape Cod Hospital
88 Lewis Bay Road
Hyannis, MA 02601

Dear Mr. Abbott:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), Office of Audit Services' (OAS) audit entitled *"Review of Medicare Transitional Pass-Through Payments Made Under the Hospital Outpatient Prospective Payment System for Drugs, Biologicals, and Medical Devices at Cape Cod Hospital for the Period August 1, 2000 through June 30, 2001."* A copy of this report will be forwarded to the action official noted below for his review and any action deemed necessary.

Final determination as to actions taken on all matters reported will be made by the HHS action official named below. We request that you respond to the HHS action official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), OIG, OAS reports issued are made available to members of the public to the extent information contained therein is not subject to exemptions in the Act. (See 45 CFR Part 5.)

To facilitate identification, please refer to Common Identification Number A-01-01-00550 in all correspondence related to this report.

Sincerely,

Michael J. Armstrong
Regional Inspector General
for Audit Services

Direct Reply to HHS Action Official:

Roger Perez
Acting Regional Administrator
Centers for Medicare and Medicaid Services – Region I
Room 2325
J.F.K. Federal Building
Boston, Massachusetts 02203

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF MEDICARE TRANSITIONAL PASS-THROUGH PAYMENTS MADE UNDER THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM FOR DRUGS, BIOLOGICALS, AND MEDICAL DEVICES AT CAPE COD HOSPITAL FOR THE PERIOD AUGUST 1, 2000 THROUGH JUNE 30, 2001

JANET REHNQUIST
Inspector General

JANUARY 2002
A-01-01-00550

Office of Inspector General

http://oig.hhs.gov/

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the Department.

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DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF INSPECTOR GENERAL

Office of Audit Services
Region I
John F. Kennedy Federal Building
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JAN 31 2002

CIN: A-01-01-00550

Mr. Stephen Abbott
President and Chief Executive Officer
Cape Cod Hospital
88 Lewis Bay Road
Hyannis, MA 02601

Dear Mr. Abbott:

This report provides the results of the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), Office of Audit Services' (OAS) audit entitled *"Review of Medicare Transitional Pass-Through Payments Made Under the Hospital Outpatient Prospective Payment System for Drugs, Biologicals, and Medical Devices at Cape Cod Hospital for the Period August 1, 2000 through June 30, 2001."* A copy of this report will be forwarded to the action official noted below for his review and any action deemed necessary.

The objective of our review was to determine whether transitional pass-through payments for drugs, biologicals, and medical devices were reimbursed in accordance with Medicare laws and regulations.

Generally, we found that the hospital was reimbursed for pass-through drugs, biologicals, and medical devices in accordance with Medicare laws and regulations. However, we did identify isolated billing issues dealing with the submission of charges for pass-through devices, units billed for pass-through drugs and incorrect coding that need to be corrected. We recommend that Cape Cod Hospital (CCH) strengthen its existing controls to ensure that pass-through payments are billed correctly.

In response to our draft report, CCH agreed with our findings and identified what steps they have taken, and plan to take, to improve controls over pass-through billing.

BACKGROUND

In August 2000, the Centers for Medicare and Medicaid Services (CMS) implemented the new prospective payment system for hospital outpatient services (OPPS). The Balanced Budget Act of 1997 amended section 1833(t) of the Social Security Act (the Act) authorizing the implementation of OPPS. The Congress enacted major changes to OPPS in 1999 under the

provides for temporary additional payments or "transitional pass-through payments" for certain innovative medical devices, drugs and biologicals for Medicare beneficiaries. The Congress intended these items to be available to Medicare beneficiaries, even if the price for these new and innovative items exceeded Medicare's regular scheduled OPPS payment amount. As a result, beginning in August 2000, when OPPS was implemented, Medicare began paying for qualified transitional pass-through items above and beyond OPPS payment rates. For drugs and biologicals, the pass-through payment is the amount by which 95 percent of the average wholesale price exceeds the applicable fee schedule amount associated with the drug or biological. For devices, the pass-through payment equals the amount by which the hospital's charges, adjusted to cost, exceeds the OPPS payment rate associated with the device.

The CCH is a 218 bed community hospital located in Hyannis, Massachusetts.

OBJECTIVE, SCOPE AND METHODOLGY

Our review was conducted in accordance with generally accepted government auditing standards. The objective of our review was to determine whether transitional pass-through payments for drugs, biologicals, and medical devices were reimbursed in accordance with Medicare laws and regulations. Based on our analysis of the CMS National Claims History file, we judgmentally selected CCH for review. To accomplish our objective we:

- Used the CMS National Claims History file to identify pass-through payments made to the hospital.

- Generated a stratified statistical sample of 100 pass-through payments for drugs, biologicals, or medical devices with dates of service between August 1, 2000 and June 30, 2001. Our sample included 70 payments for drugs and biologicals and 30 payments for medical devices.

- Reviewed applicable CMS Program Memoranda to determine the eligibility of sample drugs, biologicals and medical devices.

- Obtained an understanding of the hospital's billing process through meetings with hospital personnel.

- Reviewed the hospital's itemized bills, Medicare UB-92 claim forms, Med A Paid Claim Detail screens and pharmacy documents to ensure the sample items were billed appropriately and paid correctly by Medicare.

Our review was based on billing records. We did not review medical records to verify that sample items were actually provided and were medically necessary and appropriate.

We limited our consideration of the internal control structure to those controls concerning the accumulation of charges, creation of outpatient bills and submission of Medicare claims because the objective of our review did not require an understanding or assessment of the complete

internal control structure at the hospital.

We conducted our review at CCH in Hyannis, Massachusetts during the period September through October 2001. On December 27, 2001 we provided CCH with a copy of our draft report. Their written comments are included as an appendix to this report.

RESULTS OF REVIEW

Medicare reimbursed the hospital $122,419 for our statistical selection of 100 sample items -- $42,504 for the 70 pass-through drugs and $79,915 for the 30 pass-through medical devices. Generally, we found that the hospital was reimbursed for pass-through drugs, biologicals, and medical devices in accordance with Medicare laws and regulations. However, we did identify isolated billing issues dealing with the submission of charges for pass-through devices, units billed for pass-through drugs and incorrect coding that need to be corrected. These issues could result in both overbilling and underbilling of pass-through items by CCH.

Charges for Pass-Through Devices Included Charges for Other Medical Supplies

In three instances, CCH did not break out charges for other medical supplies from charges associated with devices eligible for transitional pass-through payments on its Medicare claim forms.
For example, billed charges for an eligible defibrillator pacemaker included defibrillator pads. Defibrillator pads are not eligible for transitional pass-through payments and their associated charges should not have been included with the charges for the eligible device.

Reimbursement for medical supplies that are not eligible for transitional pass-through payments are packaged into the Ambulatory Payment Classification (APC) payment for the associated procedure or service. Because CCH did not break out other medical supply charges, for which payment is packaged into the APC rate, these charges were inappropriately included in the transitional payment amount for the eligible devices.

Pass-Through Drugs Incorrectly Billed

For several of the drugs reviewed, the number of units billed to Medicare did not agree with the number of units dispensed according to the hospital's pharmacy records. For example, according to CMS Program Memorandum, Transmittal A-00-42, issued July 26, 2000, each 10 milligram dose of Etoposide should be billed using 1 unit of HCFA Common Procedure Coding System (HCPCS) code J9181. In one case we reviewed, the hospital billed Medicare for 10 units, or 100 milligrams, of Etoposide; however, pharmacy records indicate that 190 milligrams, or 19 units, of the drug were dispensed.

CMS MEDICARE DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS) SUPPLIER STANDARDS

Note: This list is an abbreviated version of the application certification standards that every Medicare DMEPOS supplier must meet in order to obtain and retain their billing privileges. These standards, in their entirety, are listed in 42 C.F.R. pt. 424, sec 424.57(c) and were effective on December 11, 2000.

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements.

2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.

3. An authorized individual (one whose signature is binding) must sign the application for billing privileges.

4. A supplier must fill orders from its own inventory, or must contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal procurement or nonprocurement programs.

5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.

6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare-covered items that are under warranty.

7. A supplier must maintain a physical facility on an appropriate site.

8. A supplier must permit CMS or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards. The supplier location must be accessible to beneficiaries during reasonable business hours, and must maintain a visible sign and posted hours of operation.

9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, or cell phone is prohibited.

10. A supplier must have comprehensive liability insurance in the amount of at least $300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations. Failure to maintain required insurance at all times will result in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed.

11. A supplier must agree not to initiate telephone contact with beneficiaries, with a few exceptions allowed. This standard prohibits suppliers from calling beneficiaries in order to solicit new business.

12. A supplier is responsible for delivery and must instruct beneficiaries on use of Medicare-covered items, and maintain proof of delivery.

13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.

14. A supplier must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries.

15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.

16. A supplier must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item.

17. A supplier must disclose to the government any person having ownership, financial, or control interest in the supplier.

CMS MEDICARE DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS) SUPPLIER STANDARDS (CONTINUED)

18. A supplier must not convey or reassign a supplier number; i.e. the supplier may not sell or allow another entity to use its Medicare Supplier Billing Number.

19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.

20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.

21. A supplier must agree to furnish CMS any information required by the Medicare statute and implementing regulations.

22. All suppliers of DMEPOS and other items and services must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment for those specific products and services.

23. All DMEPOS suppliers must notify their accreditation organization when a new DMEPOS location is opened. The accreditation organization may accredit the supplier location for three months after it is operational without requiring a new site visit.

24. All DMEPOS supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill the Medicare. An accredited supplier may be denied enrollment or their enrollment may be revoked, if CMS determines that they are not in compliance with the DMEPOS quality standards.

25. All DMEPOS suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation. If a new product line is added after enrollment, the DMEPOS supplier will be responsible for notifying the accrediting body of the new product so that the DMEPOS supplier can be re-surveyed and accredited for these new products.

CAPE COD HEALTHCARE

Stephen J. Guimond
Senior Vice President
& Chief Financial Officer

January 16, 2002

Michael J. Armstrong
Regional Inspector General for Audit Services
Region I
John F. Kennedy Federal Building
Room 2425
Boston, MA 02203

Dear Mr. Armstrong:

Cape Cod Hospital ("CCH") has reviewed the findings set out in Report #A-01-01-00550 (the "Report"). CCH makes every effort to report all of its services in accordance with established Medicare requirements and published guidelines. With respect to pass-through medications and devices, the late passage of the OPPS regulations and the constant changes in reimbursement status and/or eligibility make ongoing monitoring and compliance extremely difficult. Periodic training has been and will continue to be provided to all relevant CCH employees and professional staff to ensure that they remain aware of the applicable Medicare reporting requirements. Additionally, CCH will endeavor to strengthen its internal controls in the billing processes for pass-through medications and devices. With respect to CCH's under billing of Etoposide (a pass-through medication), CCH has corrected the billing software which gave rise to the under-reporting of unit doses and is grateful to the government auditors for pointing out this lost revenue.

Very truly yours,

Stephen J. Guimond
Senior Vice President & CFO

SJG: cah
via: certified mail

88 Lewis Bay Road
Hyannis, MA 02601
direct 508.862.5020
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Incorrect Coding

A pacemaker system includes a pulse generator containing electronics, a battery and one or more electrodes (leads). According to hospital officials, CCH does not perform the placement or removal of pacemaker electrodes on an outpatient basis. The hospital maintains the correct HCPCS codes for the procedures related to one of our sample items were 33213, *Insertion or replacement of dual chamber pacemaker pulse generator only*, and 33233, *Removal of permanent pacemaker pulse generator.* However, we found CCH used HCPCS code 33208, *Insertion or replacement of permanent pacemaker with transvenous electrodes(s); atrial and ventricular.*

In addition, our review of hospital invoices found that CCH billed for eligible dual chamber pacemakers when single chamber pacemakers were provided to two Medicare beneficiaries.

Although CCH billed for dual chamber pacemakers when invoices indicate that single chamber devices were provided, the single chamber pacemakers were eligible for transitional pass-through payments. Despite the fact that that hospital did appear to provide eligible devices, the use of incorrect HCPCS codes impacts the integrity of the data CMS may use to make future decisions regarding the reimbursement of transitional pass-through devices.

RECOMMENDATIONS

We believe the issues discussed above present opportunities for the hospital to further enhance its existing controls related to the accumulation of charges, creation of outpatient bills and submission of Medicare claims. Specifically, we recommend CCH:

- Strengthen its controls over the billing process to ensure that charges for pass-through devices do not include charges for other medical supplies and pacemaker procedures and eligible pass-through items are correctly coded.

- Review billing for transitional pass-through drugs to verify that billed units are proper.

AUDITEE COMMENTS

The CCH agreed with our findings and recommendations. The full text of the hospital's comments are included as the APPENDIX to this report.

Final determination as to actions taken on all matters reported will be made by the HHS action official named below. We request that you respond to the HHS action official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), OIG, OAS reports issued are made available to members of the public to the extent information contained therein is not subject to exemptions in the Act. (See 45 CFR Part 5.)

To facilitate identification, please refer to Common Identification Number A-01-01-00550 in all correspondence related to this report.

Sincerely,

Michael J. Armstrong

Michael J. Armstrong
Regional Inspector General
for Audit Services

Direct Reply to HHS Action Official:

Roger Perez
Acting Regional Administrator
Centers for Medicare and Medicaid Services – Region I
Room 2325
J.F.K. Federal Building
Boston, Massachusetts 02203